2008

ACHIEVING BALANCE in Federal and State Pain Policy

A Guide to Evaluation (Fifth Edition)

Pain & Policy Studies Group

University of Wisconsin School of Medicine and Public Health

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Executive Summary

In the United States, unrelieved pain is now considered a serious public health problem creating treatment disparities for a variety of populations of people, including children, the elderly, minorities, nursing home patients, and people with limited financial resources. At the same time another public health issue, that of opioid analgesic abuse and diversion, has gained considerable national attention through media and published reports detailing morbidity and mortality. Generally, the messages from these reports reinforce the perception that the increased prescribing for pain in the last few years is the sole or primary cause for opioid-related morbidity or mortality. If this causal attribution is taken at face value, there is a potential for state legislatures and regulatory agencies to influence the development of drug control activities that erect barriers to practitioners' effective use of opioids for legitimate medical purposes and to patients' access to needed medications.

In addition to the current issues surrounding addiction, abuse, and diversion, a number of related barriers can interfere with the prescribing, dispensing, and administering of opioids and, ultimately, with patient access to pain relief, including:

- healthcare system issues, such as low institutional priority of pain relief and inadequacies in professional training and clinical practices,
- drug law enforcement actions, and the perception of them, creating practitioner concern about being sanctioned, and
- restrictions in controlled substances and professional practice policies.

Although many treatment options exist to relieve pain, controlled substances, including opioids such as morphine, continue to be recognized as indispensable for a variety of pain types, particularly if pain is severe. Opioids also have an abuse liability, so their production and distribution is strictly regulated under federal and state controlled substances laws. However, there is a consensus that drug control efforts should not interfere with the availability of controlled substances for legitimate medical purposes. This concept drives our following policy research efforts and promotes policy that effectively achieves these dual public health objectives: Enhance pain care and prevent drug abuse and diversion.

Policy Research

In 2000, the Pain & Policy Studies Group (PPSG) designed a policy research project and published findings from the first-ever evaluation of federal and state pain policies, entitled *Achieving Balance: A Guide to Evaluation of Federal and State Policies* (*Evaluation Guide 2000*). These findings were the result of a policy analysis based on a Central Principle of *Balance. Balance* is fundamental to international and national drug control policy and asserts that efforts to prevent diversion and abuse of opioid analgesics are important and necessary but should not interfere with medical practice and patient care. Balanced policy recognizes the need for and legitimacy of controlled substances for pain management. The PPSG ultimately developed a set of criteria based on the Central Principle of Balance and used them to identify policy language with the potential either to enhance (called "positive provisions") or impede (called "negative provisions") patient access to opioid analgesics (see Section II for more information). A team of PPSG policy researchers collected hundreds of relevant federal and state policies and used the criteria to evaluate them. The results provided evidence that the number of positive and negative provisions found in pain policies vary greatly from state to state. The evidence was presented in the form of policy Profiles for each state and the Federal government.

After 2000, a number of states created initiatives to modify their pain policies, making use of a model regulatory policy prepared by the Federation of State Medical Boards of the U.S., as well as the findings presented in the *Evaluation Guide 2000*. In order to document that policies were changing, the PPSG conducted a second evaluation of policies adopted during the three-year period following the *Evaluation Guide 2000*. PPSG updated its policy collection through March 2003, used the same criteria to evaluate all new or amended policies, and published the second edition of the *Evaluation Guide* (*Evaluation Guide 2003*). The methodology for the *Evaluation Guide 2003* was substantially the same as the first. The *Evaluation Guide 2003* presented the results of the second evaluation of federal and state policies, and included examples of positive policy language that could be adopted to further improve state policies.

In July 2003, the *Evaluation Guide 2003* was published, followed in September by a *Progress Report Card (2003). The Progress Report Card 2003* compared the results from the *Evaluation Guide 2003* with the results from 2000, using a grade that was calculated based on the quality of each state's policy environment at those two points in time. As a result, the *Progress Report Card 2003* presented a single metric (a state grade) that can be used to measure change in a state's pain policies over time. The *Progress Report Card 2003* also described in some detail the positive changes that occurred in state pain policy between 2000 and 2003.

In 2006, an updated *Evaluation Guide* and *Progress Report Card* were made available electronically as the first in a series of three annual policy evaluation reports. This new evaluation began using a modified methodology that evaluated a greater variety of policies, which carries over to all subsequent evaluations. As a result, findings from previous policy evaluations are considered obsolete. A general press release, with a list of Frequently Asked Questions about pain and policy issues, was distributed to national health reporters, and individualized press releases were created for states that had grade improvements. This process was repeated in 2007 to update the reports and communicate further grade improvement

To provide current information about states' pain policies, the PPSG conducted a new evaluation of policies current as of March 2008, resulting in this report (entitled *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation, Fifth edition* (*Evaluation Guide 2008*)). The policy evaluation findings also were used to calculate grades for each state for 2008, included in a companion report entitled *Achieving Balance in State Pain Policy: A Progress Report Card, Fourth edition* (*Progress Report Card 2008*).

PPSG Evaluation Resources for Pain Policy:

2000
Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation

2003
Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (2nd edition)
Achieving Balance in State Pain Policy: A Progress Report Card

2006
Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (3rd edition)
Achieving Balance in State Pain Policy: A Progress Report Card (2nd edition)

2007
Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (4th edition)
Achieving Balance in State Pain Policy: A Progress Report Card (3rd edition)

2008
Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (5th edition)
Achieving Balance in State Pain Policy: A Progress Report Card (4th edition)

Commentary

The *Evaluation Guide 2008* is not a "position statement" about pain policies. Rather, it is the result of an ongoing research program to systematically analyze public policy affecting pain relief and the use of pain medications, and to disseminate the results. While recognizing that states take different approaches to policy formulation, we assert that there is a Central Principle that should guide efforts to establish a balanced regulatory environment for pain management. Achieving this goal does not mean that all state policies must look alike; rather, laws must strike an appropriate balance between appropriately governing controlled medications and those who prescribe and dispense, and ensuring their availability for those who legitimately need them for the relief of pain and suffering.

The pain problem has drawn the attention of a variety of professions, including medicine, pharmacy, nursing, social work, law, state law enforcement, and bioethics. In addition, professional, private, and public organizations are developing patient information and professional education resources, and calling for the removal of legislative and regulatory barriers. As an increasing number of individuals and organizations turn their attention toward the policy interface between the drug control/practice regulation and efforts to relieve pain, it is our hope that they will make use of the State Profiles from the *Evaluation Guide 2008*, the *Progress Report Card 2008*, and the many other relevant resources that are provided in this document and elsewhere on the PPSG website at www.painpolicy.wisc.edu.

There can be pitfalls and unintended consequences in reforming laws, regulations, and other agency policies. Changes in policy can advance or retard progress, depending on the content and clarity of the policy and the extent of collaboration among stakeholders during policy development. In addition, the level of effort devoted to communicating current or new policies to the stakeholders can have a direct impact on the influence of the policy; policy change with no implementation, even when the policy's message is clear and positive, may contribute little to influencing practice and care. Policy change aimed at the healthcare professions and improving practice should be accompanied by a sustained commitment to repeated dissemination and incorporation into effective professional and public education, guidelines, and patient care standards. A state's policy must not only *be* balanced, but *understood* as balanced.

Acknowledgement of Support

The PPSG remains grateful to the Robert Wood Johnson Foundation for providing resources to produce the first *Evaluation Guide in 2000*, as well as the second *Evaluation Guide* and the first *Progress Report Card* in 2003. Developing the *Evaluation Guide 2006, 2007, and 2008* and the *Progress Report Card 2006, 2007, and 2008* was supported by "Benchmarking State Policies for Cancer Pain and Palliative Care" (SIRSG-06-095-01) from the American Cancer Society, a grant from Susan G. Komen for the Cure, and through a cooperative agreement with the Lance Armstrong Foundation.

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The Principal Investigator for this project was Aaron M. Gilson, MS, MSSW, PhD, Director, U.S. Program. PPSG staff members who contributed to the project are David E. Joranson, MSSW, Distinguished Scientist and Founder of the PPSG; Martha A. Maurer, MSSW, MPH, Policy Analyst; Karen M. Ryan, MA, Director, International Program; and Jody P. Moen, BA, Policy Analyst and Communications Coordinator.

Notes to the Reader

This project was supported by "Benchmarking State Policies for Cancer Pain and Palliative Care" (SIRSG-06-095-01) from the American Cancer Society, a grant from Susan G. Komen for the Cure, and through a cooperative agreement with the Lance Armstrong Foundation.

This document is one product of the ongoing policy research program of the Pain & Policy Studies Group. Our purpose for making these data available is to promote education and policy change. We ask that anyone who wishes to use the policy data published herein for the purposes of research seek permission from the PPSG.

Policies are in constant flux, and the results presented herein pertain to policies adopted through March 2008. Also, the material in this report does not represent legal or medical advice. Individuals who need to know the current policy for legal or advocacy purposes should double-check the current status of any policies in question; PPSG is happy to assist individuals in locating the current policies.

This Evaluation Guide and its companion Progress Report Card are available on the PPSG website at www.painpolicy.wisc.edu. Comments and suggestions are welcome and may be directed to:

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SECTION I:
Purpose and Audience

PURPOSE

This is the fifth edition of *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation* (*Evaluation Guide 2008*); its purpose, as with all previous editions, is to promote more balanced and consistent U.S. federal and state policy relating to the use of controlled substances for the medical management of pain generally and specifically in palliative and end-of-life care. This purpose is accomplished by providing an updated evaluation of current federal and state policy[1] using a methodology that was conceptualized, developed, and tested over a 15 year period (Gilson, Maurer, & Joranson, 2005). The *Evaluation Guide 2008*, used in conjunction with *Achieving Balance in State Pain Policy: A Progress Report Card (Fourth Edition)*, provides a framework for deciding which policies should be removed, as well as recommended language to guide the development of new and more balanced policies. Balance in pain policy can be achieved and maintained if policymakers, healthcare professionals, and regulatory agencies work together and take advantage of the policy resources that are available. In this way, we can establish a more positive legislative, regulatory, and practice environment for the relief of pain in all patients, including those who are challenged by cancer, HIV/AIDS, sickle-cell anemia, and other painful conditions. To accomplish this goal, the *Evaluation Guide 2008*:

(1) provides updated background information about pain policy (see Appendix B for recommended readings),

(2) explains the Central Principle of Balance and the sources of authority from which it is derived, and explains the criteria that were used to evaluate policy for the presence or absence of provisions that have the potential to either positively or negatively affect pain management,

(3) presents the results of a criteria-based evaluation of identified federal and state policies that were current as of March 2008, and

(4) offers examples of language that can be used to achieve more balanced policies.

USING POLICY EVALUATION TO INFORM POLICY CHANGE

Interested parties can use the *Evaluation Guide 2008* to learn about pain policies at the state or federal level and to guide their own evidence-based review of changes that may be needed to achieve more balanced policy. This document provides the results from a transparent evaluative framework, which can help shape an action plan to remove impediments and add positive provisions in federal and state policy.

The individual provisions identified by this evaluation are not weighted or adjusted to reflect their importance or severity. Although it is possible that some provisions may influence practice or care more than others, PPSG did not believe there was enough information available at this time to warrant the development of a valid weighting protocol. Instead, PPSG recommends that the relative importance of individual provisions be taken into consideration by those who are developing action plans to improve state policy.

[1] Policy includes federal and state statutes and regulations, as well as other governmental policies issued by state professional licensing agencies (see Section II for a definition of policy types and Section IV for a description of the specific policies evaluated for this report).

In a state where significant impediments have been identified, it may be important to amend restrictive statutes or regulations as soon as possible. In other cases, it may be prudent to work with professional licensing boards to adopt and disseminate guidelines or policy statements that promote a balanced approach to pain management. In still other cases, it may be wise to initiate a broad-based study of the options to determine priorities prior to acting (Appendix C presents a discussion of the role of state legislatures and an article about task forces or study commissions that have been established by legislatures). In all cases, policy improvement must be understood as being a means to an end, and so policy must be disseminated and implemented to be useful (Connecticut Cancer Pain Initiative & American Cancer Society New England Division, 2003; Joranson, Gilson, & Nischik, 2002; Pain & Policy Studies Group, 2008). The Evaluation Guide 2008 is a tool that can be used by government and non-government organizations, as well as policymakers, healthcare professionals, and advocates, to understand the policy in their state that reinforce the right to pain management and those that can hinder patient access to effective treatment.

This is an analysis of policy content, and is not a statement of a "position." It is possible, however, that others may find policy language in addition to what we identified, or may disagree with our interpretation of the language or how we have applied the criteria; PPSG is eager to have comments from other interested parties about this work.

AUDIENCE

The intended audience for the *Evaluation Guide 2008* is individuals or organizations interested in improving pain, palliative care, or end-of-life care policy, including:

- state professional licensing boards
- state legislatures and Attorneys General
- the Congress and federal agencies
- associations of healthcare professionals
- multidisciplinary advisory councils and task forces
- state or regional pain and palliative care initiatives
- national cancer, HIV/AIDS, and pain foundations.

SECTION II:
Policy Research Terms

USE OF PAIN POLICY RESEARCH TERMS

"**Pain policy**" refers to federal or state policy that relates to pain management, and is generally found in two categories:

"Pain-specific" policies directly address pain and its management, such as medical board pain management guidelines.

"Pain-related" policies do not directly address pain management but contain provisions that could ultimately affect its treatment, such as state acts that address generally the prescribing and dispensing of controlled substances.

Within pain policies are:

"**positive provisions,**" which are those parts of a policy identified in the evaluation that have the potential to enhance pain management, and

"**negative provisions,**" which are those parts of a policy identified in the evaluation that have the potential to impede pain management.

TYPES OF POLICIES

There are several types of policies. For the purpose of this evaluation they are characterized as follows:

"Law" is a broad term that refers to rules of conduct with binding legal force adopted by a legislative or other government body at the international, federal, state, or local levels. Law can be found in treaties, constitutional provisions, decisions of a court, and include both statutes and regulations. The most common laws are the statutes enacted by a legislature, such as an Intractable Pain Treatment Act, or those that create prescription monitoring programs or pain advisory councils, or regulations that license healthcare facilities.

A **"regulation"** is an official policy issued by an agency of the executive branch of government pursuant to statutory authority. Regulations are found in the state administrative code. Regulations have binding legal force and are intended to implement the administrative policie of a statutorily-created agency. For example, regulations issued by licensing boards, according to a state's administrative procedures statute, govern professional conduct and establish what conduct is or is not acceptable for those regulated by the agency (such as physicians, osteopaths, pharmacists, and nurses). Regulations of state agencies may not exceed the agency's statutory authority (see Appendix D for further discussion).

A **"Guideline"** is an officially-adopted policy issued by a government agency to express the agency's attitude about, or position on, a particular matter. While guidelines do not have binding legal force, they may help those regulated by an agency to better understand the regulating agency's standards of practice. A number of state medical boards have issued guidelines regarding the medical use of opioid analgesics, which describe conduct the board considers to be within the professional practice of medicine (some pharmacy and nursing boards have issued similar guidelines). Guidelines may also include an officially adopted position statement that appears in a position paper, report, article, letter or agency newsletter.

SECTION III:
Background about Pain Relief and Public Policy

Unrelieved Pain Continues to Burden Americans

Pain remains one of the most common physical complaints upon a person's admission into the healthcare system (Burton, Fanciullo, et al., 2007; Foley, Back, et al., 2005; Furrow, 2001; Kutner, Kassner, et al., 2001; Lazarus & Neumann, 2001; Weiss, Emanuel, et al., 2001). Pain is prevalent in cancer, especially near the end of life, and in other diseases and conditions such as HIV/AIDS and sickle-cell anemia. Unfortunately, pain often is not treated adequately. Inadequate pain management can impair all aspects of life and sometimes lead to a person's wish for death (Institute of Medicine Committee on Care at the End of Life, 1997; Institute of Medicine National Cancer Policy Board, 2001). Sufficient pain relief can result in improved quality of living for people with chronic pain and can decrease suffering for people at the end of life.

International organizations have provided valuable guidance with regard to the policy implications of health care. In 1966, the United Nations (UN) General Assembly's International Covenant on Civil and Political Rights recognized that every person has a right to the highest attainable standard of physical and mental health (United Nations General Assembly, 1966). In more recent years, several international authorities, including the UN Economic and Social Council (ECOSOC), the World Health Organization (WHO), the World Health Assembly (WHA), and the Council of Europe have recognized pain relief as an important public health issue and, indeed, a universal human right.

There are many pharmacologic and non-pharmacologic treatments that are useful to relieve pain (Cleary, 2007; Dworkin, O'Connor, et al., 2007; Fine, Fanciullo, et al., in press; Miaskowski, Cleary, et al., 2005; World Health Organization, 2000). Opioid analgesics in the class of morphine are effective for medical use (Federal Food, Drug, and Cosmetic Act, 21 USCS § 301 et seq.) and essential for the medical management of moderate or severe pain (World Health Organization, 1996). Opioids must be available in adequate amounts when and where patients need them, especially when pain is severe (Fine & Portenoy, 2007; Katz, McCarberg, et al., 2007; World Health Organization, 1990). Physicians, osteopaths, pharmacists, and nurses (where allowed) must be able and confident to prescribe, administer and dispense opioids, according to individual patient needs (World Health Organization, 1996).

Many factors contribute to the continued prevalence of unrelieved pain in the U.S., including characteristics of the healthcare system and healthcare professionals. Most studies have focused on issues in the clinical domain, such as: (1) knowledge and attitudes of healthcare professionals about the legitimate use of opioids (Furstenberg, Ahles, et al., 1998; Hollen, Hollen, et al., 2000; Joranson & Gilson, 2001; Lin, Alfrande, et al., 2007; McMillan, Tittle, et al., 2000; Passik, Byers, et al., 2007; Portenoy, Sibirceva, et al., 2006; Roth, Burgess, et al., 2007), (2) patient and family perceptions about the use of opioids for pain relief (Breitbart, Passik, et al., 1998; Drayer, Henderson, et al., 1999; Institute of Medicine National Cancer Policy Board, 2001; McCracken, Hoskins, et al., 2006; Rhymes, 1996; Tolle, Tilden, et al., 2000a; Ward, Goldberg, et al., 1993), and (3) the inadequate clinical use of opioids in certain patient populations (Cintron & Morrison, 2006; Heins, Grammas, et al., 2006; Morrison, Wallenstein, et al., 2000; Pletcher, Kertesz, et al., 2008; Rolnick, Jackson, et al., 2007; Schwaderer & Itano, 2007). Restrictive drug-related public policies, as well as concerns about regulatory scrutiny when prescribing controlled substances, have also been recognized as significant impediments to pain relief (Cancer Pain Management Policy Review Group, 2001a; Gilson, Maurer, et al., 2005; Institute of Medicine, 1997; Joranson & Gilson, 2001, 2003; Joranson, Gilson, et al., 2000; McErlean, Triner, et al., 2006; Miaskowski, Cleary, et al., 2005; National Association of Attorneys General, 2003a, 2003b; National Institutes of Health Consensus Development Program, 2002; Taylor, Gostin, et al., 2008; Tucker, 2001).

The Public Health Problem of Prescription Opioid Abuse and Diversion

In recent years there has been a growing recognition that increases in the availability of prescription opioids indicated for the treatment of severe pain have co-occurred with more prevalent non-medical use and diversion of these medications (Cicero, Inciardi, et al., 2005; Compton & Volkow, 2006; Gilson, Ryan, et al., 2004; Novak, Nemeth, et al., 2004; Paulozzi & Budnitz, 2006; Peindl, Mannelli, et al., 2007; Zacny, Bigelow, et al., 2003). However, the extent that opioid medication abuse and diversion occurs within the context of pain management remains unclear. There is not yet a comprehensive understanding of how prescription opioids that are available for medical use are reaching illicit channels.

Identified abuse and diversion of prescription opioid medications frequently is attributed solely to increased prescribing, resulting in a preponderance of messages focusing only on the dangers of opioid use while neglecting their medical benefit; typically this conclusion is made without direct evidence of a causative relationship. If such an attribution is accepted uncritically, and abuse and diversion is primarily considered a prescribing problem, likely responses will include monitoring healthcare professionals' practices (as well as the patients who receive the medications) and unduly limiting prescriptions or severely tightening requirements (Joranson & Gilson, 2006). This narrow approach also fails to recognize that there can be non-medical sources of diversion that completely eschew the practitioner/patient relationship (Joranson & Gilson, 2005). A thorough understanding of the abuse and diversion problem is essential in order to prevent drug control efforts that end up using limited resources that have little or no benefit in minimizing abuse or diversion or that can actually obstruct the availability of medications for the patients who need them.

Balancing Control and Availability

Because opioid analgesics also have a potential for abuse, their prescribing and dispensing, indeed their very availability in commerce, is governed by a combination of policies, including international treaties and U.S. federal and state laws and regulations. The main purpose of these policies is **drug control**: to prevent diversion and abuse of prescription medications. However, international and federal policies also express clearly a second purpose of drug control, that being **availability**: recognizing that many opioids (referred to in law as narcotic drugs or controlled substances) are necessary for pain relief and that governments must ensure their adequate availability for medical and scientific purposes. When both control and availability are appropriately recognized in public policy, and *implemented* in everyday practice, this is referred to as a **balanced** approach (Fine & Portenoy, 2007; Gilson, in press; Gilson, Joranson, et al., 2005; Joranson & Gilson, 2003).

To accomplish the desirable balance between availability and control, the international drug control authorities associated with the UN have asserted that efforts to prevent drug abuse and diversion should not interfere with the availability and medical use of controlled drugs (United Nations, 1977); indeed, the WHO (2000) has published evaluation guidelines to achieve balanced national opioids control policies (see Section V and Section VI for a detailed discussion of Balance and the imperative to create balanced healthcare policy). In addition, the UN ECOSOC has emphasized the importance of treating pain while taking into account the need to prevent drug diversion (United Nations Economic and Social Council, 2005a). Finally, the WHA (2005) urged Member States:

> *"…to ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Narcotics Control Board and subject to an efficient monitoring and control system"* (p. 3).

The federal Controlled Substances Act (CSA) establishes the U.S. system of drug control that is also intended to accomplish availability through a set of laws and regulations (see Types of Policies in Section II) that governs drug importation, manufacture, and distribution. Licensed and registered professionals may prescribe, dispense, and administer controlled drugs for legitimate medical purposes in the course of professional practice[2] (Code of Federal Regulations, Title 21 §1306.04(a); Controlled Substances Act, Title 21 §826(a)). To prevent diversion, the CSA establishes a closed system of licensing, security, record keeping, monitoring, and penalties (Drug Enforcement Administration, 2004; Drug Enforcement Administration, 2006). For example, Schedule II drugs require a written prescription and cannot be refilled; however, there are no federal statutory restrictions on dosages or quantities of drugs prescribed (Drug Enforcement Administration, 2006; November 2007). Federal controlled substances law recognizes that many controlled substances are necessary to maintain health and establishes a procedure for ensuring that these medications are adequately available to satisfy prescription demand. The CSA is not intended to interfere with medical practice or with the availability of controlled substances approved under the FFDCA for legitimate medical purposes (Controlled Substances Act, Title 21 §902; Joranson & Gilson, 1994; Noah, 2003). The CSA does, however, contain an archaic definition of "addiction," but the definition has little potential to confuse patients using opioids for pain treatment with persons who compulsively use opioids non-medically due to an addictive disease, and is not considered a potential barrier to adequate pain relief.

State Policies May Be More Restrictive

In addition to federal requirements, controlled substances prescribing, dispensing, and administration is regulated by the states. States are responsible for regulating healthcare practice, including medical, osteopathic, and pharmacy practice. State policies tend not to be as balanced as international and federal policy (Gilson, in press; Gilson, Maurer, et al., 2005); unlike federal law(Controlled Substances Act, Title 21 §801(1)), most state laws do not specifically recognize the public health importance of controlled drugs. In addition, some state laws or other governmental policies restrict prescribing and dispensing of opioids to a greater extent than federal law, and can interfere with medical decisions that should be based on individual needs of the patient and medical expertise, rather than government mandate.

Beginning in Wisconsin in the mid-1980s, studies by various groups and individuals began identifying regulatory impediments to pain management in state policies (Dahl & Joranson, 1987; Hill, Jr., 1989; Joranson & Dahl, 1989; Joranson, 1990a; Joranson & Gilson, 1996, 1997; Von Roenn, Cleeland, et al., 1993). A succession of reports and articles on inadequate pain management has identified the possible influence of policy impediments at the state level (Cancer Pain Management Policy Review Group, 2001a, 2001b; Federation of State Medical Boards of the United States Inc., 1998, 2004; Fujimoto, 2001; Gilson, Maurer, et al., 2005; Institute of Medicine Committee on Care at the End of Life, 1997; Merritt, Fox-Grage, et al., 1998; Miaskowski, Cleary, et al., 2005; National Conference of Commissioners on Uniform State Laws, 1990, 1994; National Institutes of Health Consensus Development Program, 2002; Rich, 2000; Tucker, 2001). The American Cancer Society (ACS) (Cancer Pain Management Policy Review Group, 2001a), as well the Institute of Medicine (Institute of Medicine Committee on Care at the End of Life, 1997) and the National Institutes of Health (National Institutes of Health Consensus Development Program, 2002), have called for studies to improve pain management by identifying the legal and regulatory impediments to using opioids for pain relief. In addition, international organizations, such as the International Narcotics Control Board (1996) and the World Health Organization (1990, 1998a, 2000), have called on all countries to identify and address regulatory barriers to cancer pain relief.

[2] The use of opioids to treat opioid addiction is not legitimate medical practice unless accomplished according to federal and state laws that regulate this practice.

Regulatory impediments include unduly strict limitations on prescribing and dispensing, exclusion of substance abusers from receiving prescriptions for pain medications, and legal terminology that confuses physical dependence on opioids used in the course of pain therapy with opioid addiction, which is heavily stigmatized in the U.S. and is primarily associated with illegal activity (Cicero, Inciardi, et al., 2005; Inciardi, Surratt, et al., 2007; Joranson & Gilson, 2005). Many of the restrictive provisions in state policies were enacted 20 or more years ago, and are likely based on outdated information about pain, opioids, and addiction.

STATE POLICIES ARE CHANGING

In the last two decades, efforts by a variety of individuals, state pain, cancer, and end-of-life care initiatives, patient groups, and state agencies have begun to reform state pain policy (Gilson, Joranson, et al., 2005; Gilson, Joranson, et al., 2003, 2007; Gilson, Maurer, et al., 2005). Figure 1 illustrates the growing number of state pain-specific policies, such as medical board guidelines and Intractable Pain Treatment Acts (IPTAs). Policy reform often produces more balanced state policies, but in some cases can also create additional restrictions and requirements that have the potential to impede pain management.

IPTAs are statutes intended to improve access to pain management by providing physicians immunity from regulatory sanctions for prescribing opioids to patients with intractable pain. However, many IPTAs also have imposed *more* requirements and restrictions on opioid prescribing for pain (American Alliance of Cancer Pain Initiatives, 2004). Immunity under an IPTA may not apply to physicians who prescribe to patients whose pain does not satisfy the definition of "intractable pain." Some IPTAs suggest that the use of opioids for "intractable pain" is not within the ordinary practice of medicine, and may have the effect of greater rather than less government regulation over the use of controlled substances to manage pain. In addition, IPTAs typically do not contain clear statements that are aimed at enhancing pain management and access to care. Some states have recognized these characteristics and have worked to remove ambiguities and restrictions from IPTAs. For example, in 2001 Michigan became the first state to delete the term "intractable pain" from its statute, thus making its provisions applicable to pain in general. More recently, both California (the state with the second-oldest IPTA) and Rhode Island repealed a number of restrictive provisions from their IPTAs, including removing the term and definition of "intractable pain;" in the last year, Oregon also repealed the definition of "intractable pain" from its IPTA. The resulting laws now govern the treatment of all types of pain. In addition, in 2006 Arkansas adopted a new IPTA that generally eschewed the numerous instances of restrictive or ambiguous policy language found in past IPTAs; Arkansas's IPTA does, however, prohibit prescribing to patient with pain who also had an addictive disease. Instead of statutes, many states have chosen to develop guidelines or regulations containing language aimed at enhancing pain management.

From 1994 to 1998, and again between 2004 and 2005, state medical boards participated in pain management workshops sponsored by the PPSG and the Federation of State Medical Boards of the U.S. (the Federation) and began adopting guidelines and regulations to encourage better pain management and to address physicians' concern about investigation (Gilson & Joranson, 2002; Gilson, Maurer, et al., 2005, 2007; Joranson, Gilson, et al., 2002). To promote consistency in state medical policy, the Federation adopted in 1998 *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (*Model Guidelines*). In May 2004, the Federation's House of Delegates unanimously adopted a revision of the *Model Guidelines*, called the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (*Model Policy*) (see Appendix A). The revision is substantially similar to the 1998 guidelines, but also encourages state boards to address failure to treat pain as subject to professional discipline, which has been identified as an important need for state policy (Tucker, 1998, 2003). At this time, 32 states have adopted or adapted either the *Model Guidelines* or *Model Policy* (Figure 1).

The trend to adopt state medical board policy statements on pain management has resulted in positive changes in state pain policies (Gilson, in press; Gilson, Joranson, et al., 2003) and also in efforts to communicate them to practitioners and the public (Gilson, Joranson, et al., 2007; Hoffmann & Tarzian, 2003).

State-level advocacy initiatives to enhance pain management practices and end-of-life care have emerged in the form of task forces, pain commissions, and advisory councils. Many of these initiatives have as their goal to improve pain management practices in their state by, in part, evaluating the laws that impact patients' access to adequate pain relief and develop a plan to remove any identified regulatory barriers (Abrams, 2006; Gilson, 2007; Maryland State Advisory Council on Pain Management, 2004;Michigan Department of Consumer and Industry Relations, 2002; New York State Public Health Council, 1998). Medical, osteopathic, pharmacy and nursing boards in some states have adopted jointly-prepared guidelines for pain management, palliative care, and end-of-life care (Pain & Policy Studies Group, 2003, 2006, 2007). Improving pain, palliative care and end-of-life care policy has also been the focus of groups such as the Alliance of State Pain Initiatives (ASPI) (formerly the American Alliance of Cancer Pain Initiatives) (Dahl, Bennett, et al., 2002), the ACS (Cancer Pain Management Policy Review Group, 2001b; Connecticut Cancer Pain Initiative & American Cancer Society New England Division, 2003), the American Society of Law, Medicine & Ethics (Johnson, 2003), the Institute of Medicine (Institute of Medicine Committee on Care at the End of Life, 1997), the National Association of State Controlled Substances Authorities (1999), the National Association of Attorneys General (2003a), and the National Institutes of Health (National Institutes of Health Consensus Development Program, 2002; 2004).

Improving state policy, like any other factor related to pain management, is not usually sufficient in and of itself to accomplish effective pain relief, but it is a necessary component to achieving a positive professional practice and regulatory environment for treating pain. Policy will have an impact only to the extent that it is communicated and implemented. Even the most positive policy, with no implementation, will have little practical value. To be most effective, a new state policy should be disseminated widely and repeatedly to licensees and the public.

Unevaluated Policies can be Important to Patient Care

Each year a number of state policies are adopted that have the potential to impact patient pain care, but are not evaluated because they do not meet the inclusion criteria for this policy evaluation research (see Section IV). For example, a recent multidisciplinary clinical practice guideline from Washington state, entitled "Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain" (Agency Medical Director's Group, 2006), has received much attention from national pain organizations as a precedent for states to adopt unduly restrictive treatment policy (American Pain Foundation, 2007; American Pain Society, 2007; Peppin, 2008). At least one state commission has issued a position statement to oppose Washington's clinical practice guideline (Oregon Pain Management Commission, 2007), stating that the guideline can "…limit care and increase the burden of the patients [physicians] are mandated to assist" and "…dramatically increase the stigma and suffering of people in pain." Such reactions illustrate the belief that implementation of such a guideline would create barriers to patient access to appropriate pain treatment. Despite such concern, and the recognition that overly restrictive policies should be avoided, this policy evaluation does not apply to clinical practice guidelines and, as a result, this Washington policy was not reviewed.

As another example, on April 1, 2007, the New York legislature adopted a palliative care education and training statute (NY CLS Pub Health § 2807-n). In addition to permitting grants for both undergraduate and graduate medical education in palliative care, the legislation establishes a palliative care and training council authorized to provide information and

guidance to practitioners on advancements in palliative care treatment modalities. A report also must be submitted to the governor and the legislature detailing the effectiveness of the education and training interventions. It is evident that such a legislative mandate has a clear potential to improve palliative care services in the state of New York. However, as described throughout this report, the evaluated policies are explicitly relevant to the treatment of pain and the use of controlled substances (e.g., statutes mandating pain management education and training, such as in California). Policies promoting palliative care services, without specifically including pain management, fall outside the evaluation methodology.

The Role of Federal Drug Law Enforcement

Healthcare professionals and law enforcement share a responsibility to ensure that prescription pain medications are available to the patients who need them, while also protecting public health by preventing their abuse and diversion (Drug Enforcement Administration, Last Acts, et al., 2001). A balanced approach can be accomplished only when health professionals who treat pain understand and avoid intentionally contributing to diversion, and when law enforcement understands and does not interfere with pain management when dealing with diversion (Drug Enforcement Administration, Last Acts, et al., 2001). To this end, the pain and law enforcement communities have undertaken efforts to promote a balanced approach to pain management.

For example, in 2001 the PPSG collaborated with Drug Enforcement Administration's (DEA) Office of Diversion Control to create a joint statement, along with 21 healthcare organizations, entitled "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act;" the statement has been endorsed by over 40 healthcare organizations and is available at http://www.painpolicy.wisc.edu/Consensus2.pdf. Following this successful collaboration, in 2002 the DEA began working with the PPSG, pain and addiction medicine experts, and regulatory personnel to author an extensive educational document for healthcare professionals and DEA investigators, entitled "Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel" (FAQ). The FAQ was published in August 2004, and the DEA planned to make it available to all physicians and pharmacists in the country via the registration process, as well as to law enforcement and regulatory officials.

Soon after publication, however, DEA withdrew its support of the FAQ and issued an Interim Policy Statement (IPS) in the Federal Register on November 16, 2004. The IPS reversed the DEA's previous policy that issuing several prescriptions on the same date with notations for later dispensing (i.e., a prescription series) was legal and took issue with several other statements in the FAQ, saying it contained "misstatements of law" (Federal Register, 2004, p. 67170). Despite extensive concern from around the country, the DEA issued another statement in the Federal Register re-affirming that issuing a prescription series was illegal. DEA requested comments and indicated that a final policy statement would be forthcoming. On September 6, 2006, a Final Policy Statement was issued, along with a proposal that would allow "an individual practitioner [to] issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance" (Drug Enforcement Administration, September, 2006, p. 52726), provided that certain conditions are met. The final rule outlining the issuance of multiple prescriptions for Schedule II controlled substances was issued in November, 2007 (Drug Enforcement Administration, November, 2007, p. 64921-64930), and can be found at http://www.deadiversion.usdoj.gov/fed_regs/rules/2007/fr1119.htm. The final rule is considered an attempt by the DEA to issue a balanced policy to improve pain management while reducing the likelihood of medication abuse or diversion (Gilson & Joranson, in press).

THE IMPORTANCE OF NON-POLICY INITIATIVES

There are many important educational and organizational initiatives addressing pain relief as a healthcare priority that are not addressed in the PPSG evaluations because they are not federal or state policy initiatives. Examples include professional and public awareness presentations, the development of institutional standards, practice guidelines and cooperative efforts between state medical societies, pain initiatives, and hospice and palliative care groups.

SECTION IV:
Research Methodology

OVERVIEW

This document presents the results of a systematic, criteria-based, evaluation of policies affecting pain management that have been adopted by the federal government, the 50 states, and the District of Columbia. The PPSG evaluated federal controlled substances statutes and regulations, as well as state statutes and regulations governing controlled substances, medical, osteopathic, and pharmacy practice, and the regulation of healthcare facilities. We also evaluated other governmental policies where present, such as state medical board guidelines and official policy statements. Policies relevant to pain management and the use of controlled pain medications comprise the population studied for this research. Relevant federal policy includes the Controlled Substances Act (CSA) and Controlled Substances Regulations (Code of Federal Regulations), while keyword searches are conducted of the Federal Food, Drug & Cosmetic Act (FFDCA) and Public Health laws. Relevant state policies[3] consisted of the statutes and regulations governing controlled substances, and medical, osteopathic, and pharmacy practice, as well as other policies containing language related to pain management, such as:

- Policies authorizing or requiring healthcare facilities to assess or treat pain
- Provisions encouraging or requiring medical school education or continuing medical education related to pain management
- Provisions establishing pain commissions, councils, and task forces as governmental vehicles designed to improve pain management and the use of controlled substances (evaluation is based on the objectives stated in policy, and not on the procedures or results of the commission's work)
- Provisions authorizing or requiring regulatory agencies to create and implement rules or guidelines specifically relating to pain management, and communicating these policies to licensees.

DATA COLLECTION

An electronic legal database (Lexis, from "Lexis-Nexis Research Software") was used to identify and obtain relevant federal and state statutes and regulations. Governmental policies not available through Lexis were collected directly from the relevant state healthcare regulatory agencies. The websites of all medical, osteopathic, and pharmacy boards were accessed to determine if they contained official guidelines or policy statements that had been adopted by the board. If the policies were available electronically, they were downloaded; otherwise the medical, osteopathic, and pharmacy boards in each state were contacted to inquire about and, if necessary, obtain the policies.

Lexis also was used to perform a Boolean (i.e., key-word) search of all federal and state statutes and regulations for the presence of provisions that have the potential to impact pain management. The following terms relating to pain management, as well as addiction-related phenomenon, were used to search the federal and state policies: "Pain," "addict/addiction,"

[3] We did not did not focus the evaluation on a number of state policies that could affect pain management but fall outside the scope of our evaluation, including policies such as nursing or physician assistants practice, controlled substances scheduling, advance directives or living wills, reimbursement, worker's compensation, importation, Internet prescribing, or clinical practice guidelines. We also did not evaluate civil or administrative case law, or language from legislative notes. There are insufficient comparable authoritative sources that would support the valid application of the Central Principle of Balance and its evaluation criteria to these policies (see Section V and Section VII). However, descriptive studies of these policies in relation to pain and prescribing controlled substances would be valuable.

"dependence/dependent" (drug, substance, and physical), and "abuse" (drug, substance, narcotic, and opioid).

Data collection also was accomplished via (1) regular review of all medical, osteopathic, and pharmacy board newsletters that are available on the internet; (2) periodic updates from the National Association of State Controlled Substances Authorities; (3) regular review of newsletters such as the National Conference of State Legislatures' "State Health Notes;" (4) various email list serves; and (5) personal contacts with those who are knowledgeable about policy trends.

Despite these comprehensive data-collection procedures, however, it is possible that relevant provisions were missed. This is especially true if state laws adopted by March 2008 were not chaptered in Lexis by the time we completed the data collection phase.[4]

POLICY EVALUATION

All relevant policies that were in force and available as of March 2008 were examined for this evaluation.[5] A Central Principle has been identified and defined (see Section V), from which 16 evaluation criteria were developed and defined (see Section VII). Three of the 16 criteria (Criterion #8, Criterion #15, and Criterion #16) were created for provisions that have the potential to affect pain management but do not fit the specific criteria.

Table 1 and Table 2 list citations from the international and national authoritative sources that support the Central Principle and the criteria, as well as the imperative to evaluate pain policy. After the data collection phase, three policy analysts at the PPSG applied the criteria to evaluate all the new or revised policies that were identified. Provisions were judged to satisfy the criteria only on the basis of explicitly-stated language ("black letter policy"), not by their implication or intent.[6] For example, the overall intent of an IPTA may be to encourage pain management, but the language of the policy would need to include an explicit statement to that effect to satisfy the relevant criterion (see Criterion #4: "Pain management is encouraged").

Provisions that met any of the criteria were identified by consensus among the policy analysts. These provisions are presented in the Federal and State Profiles section (see Section VIII). If a policy contained repetitive language, so that the same criterion could be satisfied multiple times, we identified only one provision that met that criterion. For example, we did not identify repeated mentions of the same prescription requirement in a particular statute or regulation. As a result, when this *Evaluation Guide* is used to revise a policy, the entire policy must be examined to identify all occurrences of a provision that should be changed. However, Criterion #8, Criterion #15, and Criterion #16 can be applied more than once to the same policy if they represent different ideas. Once evaluated, the full text of all new and amended relevant provisions was added to a computerized database created for the previous *Evaluation Guides* (Joranson, Gilson et al., 2000; Pain & Policy Studies Group, 2003, 2006, 2007).

The Federal and State Profiles (see Section VIII) contain all relevant provisions extracted from each identified policy. Highlighting and underlining is used to draw attention to the specific language. A "comment" box identifies the criterion that was satisfied by a particular provision, using a positive (+) or negative (-) sign and shading to indicate whether the provision has the

[4] For example, a Kansas law creating a Controlled Substances Monitoring Task Force seems to have been signed by the Governor on April 9, 2007, but could not be found chaptered in the policies contained in Lexis and, therefore, was not included in this evaluation. The law will be eligible for evaluation once chaptering is confirmed.

[5] For example, the Missouri bill to repeal the term "intractable pain" from the Intractable Pain Treatment Act was not signed by the Governor as of April 1, 2008. Because its adoption date fell outside of our time period, it was not included in this study; it will be included in any subsequent evaluation.

[6] One exception is Criterion #10, which addresses policy language with an implicit message; see Section VII for the justification for this methodology.

potential to enhance (+) or impede (-) pain management. It should be noted that the effect of the provisions on pain management practice or care may vary according to how the provisions are perceived, implemented, or enforced, and is a matter for further study.

The evaluation of provisions governing controlled substances included only those relevant to Schedule II controlled substances because these are the only controlled medications approved and essential for severe pain. For example, a state may have a 5-day prescription validity period for a Schedule II medication, and a 20-day validity period for Schedule III-V medications; only the 5-day limit on Schedule II medications was considered.

SECTION V:
The Central Principle of Balance

BALANCE IS THE CENTRAL PRINCIPLE

Opioids have long been used to relieve pain and have been a part of medical practice for centuries. This fact has been recognized in international law aimed at preventing drug abuse. The Single Convention on Narcotic Drugs of 1961 is an international treaty to which most governments, including the U.S., are parties. This Convention[7] establishes that governments are obligated to ensure the availability of narcotic drugs for medical and scientific purposes and to prevent diversion, illicit trafficking, and abuse.

The Central Principle, used for all previous *Evaluation Guides*, is the same as for this evaluation. It was developed by the PPSG and is stated as follows:

> The Central Principle of ***Balance*** represents a dual imperative of governments to establish a system of controls to prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time, ensuring their medical availability. While opioid analgesics are controlled drugs, they are also essential drugs and are absolutely necessary for the relief of pain. Opioids, including those in the therapeutic group of morphine, should be accessible to all patients who need them for relief of pain. Governments must take steps to ensure the adequate availability of opioids for medical and scientific purposes. These steps include empowering medical practitioners to provide opioids in the course of professional practice, allowing them to prescribe, dispense and administer according to the individual medical needs of patients, and ensuring that a sufficient supply of opioids is available to meet medical demand.
>
> When misused, opioids pose a threat to society; a system of controls is necessary to prevent abuse, trafficking, and diversion, but the system of controls is not intended to diminish the medical usefulness of opioids, nor interfere in their legitimate medical uses and patient care. Indeed, governments have been asked to identify and remove impediments to the availability and medical use of opioid analgesics.

It is recognized that the adequacy of *controls* to prevent diversion and abuse of controlled substances is also a valid topic for policy evaluation. The evaluation and refinement of federal and state drug *control* policy occurs frequently, but the *Evaluation Guide* is the only systematic criteria-based methodology available for evaluating U.S. drug control policies as they affect *availability* and *medical use* of opioids. Thus, the purpose of this guide is to evaluate policies affecting availability and not drug trafficking and abuse prevention.

[7] In addition, the Convention on Psychotropic Substances of 1971 established a similar imperative for balanced policy concerning psychotropic drug policy.

THE RATIONAL BASIS FOR THE CENTRAL PRINCIPLE OF BALANCE

The validity of policy analysis depends on the relevance and credibility of the evaluation criteria (Patton & Sawicki, 1993). Evaluation criteria should be based on principles, determinations, or recommendations that have been accepted by the highest possible authorities in the field.

The following excerpts from international and national legal and medical authorities establish the Central Principle of Balance (see Table 1 and Table 2).

International authorities

The Single Convention on Narcotic Drugs of 1961 stated that:

> *"the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering...adequate provision must be made* [by governments] *to ensure the availability of narcotic drugs for such purposes"* (United Nations, 1977, p. 13).
>
> *"The Parties* [national governments] *shall take such legislative and administrative measures as may be necessary...to limit exclusively to medical and scientific purposes the production, manufacture...distribution... and possession of drugs"* (United Nations, 1977, pp. 18-19).

The International Narcotics Control Board (2006), which implements the Single Convention of Narcotic Drugs, continues its call for adequate amounts of needed medications:

> *"Another objective of the international drug control treaties is to ensure the availability of narcotic drugs and psychotropic substances for medical treatment and to promote the rational use of controlled drugs*" (p. 93).

In addition, the International Narcotics Control Board (2007) stated that:

> *"The Board again requests all Governments to promote the rational use of narcotic drugs for medical treatment, in accordance with the pertinent recommendations of WHO"* (p. 12).

A WHO Expert Committee (1986) devised and recommended to all governments a simple, medically, and scientifically sound approach to treating cancer pain that depends on the availability of opioids such as codeine and morphine. The WHO Expert Committee on Essential Drugs (1998b) has for many years designated morphine, codeine, and other opioids as "essential drugs," defined as:

> *"those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms..."* (p. 2).

With respect to medical decisions regarding the care of individual patients, the WHO (1996) recognized that:

> *"Decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, and not by regulation"* (p. 58).

The WHO (2000) prepared guidelines for evaluating national opioids control policy that are also based on the Central Principle of Balance:

> *"These Guidelines can be used by governments to determine whether their national drug control policies have established the legal and administrative framework to ensure the medical availability of opioid analgesics, according to international treaties and the recommendations of the INCB and the WHO... [and] to encourage governments to achieve better pain management by identifying and overcoming regulatory barriers to opioid availability"* (pp. 1-2).

Even more recently, the WHO (2004) recognized that:

> *"...access to pain relief and palliative care services is often limited, even in high-resource settings, because of...excessive regulation of opioids (p. 3) [and] urges Member States...to ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Control Board"* (p. 6).

In 2006, the WHO Expert Committee on Drug Dependence addressed the negative impact that overly-restrictive drug control efforts can have on medical availability:

> *"During the discussions, factors limiting the availability of drugs for medical use were identified, including barriers inadvertently created by the application of laws and regulations. There are countries where stricter measures are applied than are required by the Conventions. This is permissible, as the requirements of the Conventions are minimum requirements. However, the aims of the Conventions are to ensure availability for medical use as well as the prevention of abuse. It should be noted therefore that the Conventions do not require the parties to implement specific licensing for prescribing and dispensing controlled substances for medical use, nor require permits for receiving these substances therapeutically. Applying stricter measures than those required by the Conventions may hamper rational use of medicines. The appropriate national authorities should carefully consider whether any such measure currently in force could be modified to permit access for patients in need...The Committee requested the WHO Secretariat to suggest including on the proposed agenda of the next Committee meeting, a discussion of the impact of scheduling on the balance between medical availability of controlled substances and the prevention of their abuse"* (pp. 20-21).

The UN Economic and Social Council (2005b) addressed the demand for and supply of opioid analgesics for medical purposes, and:

> *"...Recognize[s] that the medical use of narcotic drugs, including opiates, is indispensable for the relief of pain and suffering [and]...the need to balance the global licit supply of opiates against the legitimate demand for opiates used to meet medical and scientific needs is central to the international strategy and policy of drug control"* (p. 1).
>
> Urges all Governments to continue to contribute to maintaining a balance between the illicit supply of and demand for opiate raw materials used for medical and scientific purposes..." (p. 2).

The UN Economic and Social Council (2005a) also addressed the treatment of pain using opioid analgesics, and:

> *"...Recognizes the importance of improving the treatment of pain, including by the use of opioid analgesics, as advocated by the World Health Organization, especially in developing countries, and calls upon Member States to remove barriers to the medical use of such analgesics, taking fully into account the need to prevent their diversion for illicit use"* (p. 2).

National authorities

In the U.S., a number of opioid analgesics have been accepted as effective, essential, and legal to be prescribed for human use under the FFDCA.[8] The FFDCA does not specify or recommend maximum dosages or quantity of prescription (Federal Register, 1975; Joranson & Gilson, 1994). Neither does the FFDCA regulate medical practice, a matter that is left to the states (a lower court decision that is referenced in United States v Evers, 1981). At both the federal and state levels, opioid analgesics are regulated as controlled substances because they have a potential for abuse.

Upon adoption of the CSA, the Congress declared:

> *"Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people"* (Controlled Substances Act, Title 21 §801(1)).

Manufacturers are registered by the Department of Justice Drug Enforcement Administration (DEA), not only to maintain effective controls against diversion but also to:

> *"...produce an adequate and uninterrupted supply of these substances..."* (Controlled Substances Act, Title 21 §823a(1)).

[8] Reidenberg (2006) has urged the healthcare field to discontinue using the term "drug safety," as no prescription medication is absolutely safe and all pose some safety and health risks. Rather, all drugs have adverse effects, which the FDA consider acceptable risks relative to the medication's benefits when used as directed under the supervision of a licensed and registered practitioner.

An administrative law judge for the DEA declared:

> *"The CSA requirement for a determination of legitimate medical need is based on the undisputed proposition that patients and pharmacies should be able to obtain sufficient quantities...of any Schedule II drug, to fill prescriptions. A therapeutic drug should be available to patients when they need it..."* (Federal Register, 1988, p. 50593).

To clarify that the medical use of opioids for pain management is a legitimate medical purpose, the DEA, which implements the CSA throughout the U.S., declared in a regulation that:

> *"This section is not intended to impose any limitations on a physician or authorized hospital staff to...administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts"* (Code of Federal Regulations, Title 21 §1306.07(c)).

In the *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, the Federation (2004) reaffirmed the central role of the physician in making decisions about the use of opioids:

> *"Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice"* (p. 6).

The Federation (2004) also stated that:

> *"...principles of quality medical practice dictate that the people...have access to appropriate and effective pain relief...physicians [should] view pain management as a part of quality medical practice for all patients with pain...All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances...controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins"* (p. 5).

In 2001, DEA and 21 leading health organizations endorsed a joint statement, *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*, resulting in explicit language promoting balance:

> *"Preventing drug abuse is an important societal goal, but there is consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients' ability to receive the care they need and deserve."*
>
> *"Undertreatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death. Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively."*
>
> *"For many patients, opioid analgesics – when used as recommended by established pain management guidelines – are the most effective way to treat their pain, and often the only treatment option that provides significant relief."*
>
> *"Drug abuse is a serious problem. Those who legally manufacture, distribute, prescribe and dispense controlled substances must be mindful of and have respect for their inherent abuse potential. Focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated – generating a sense of fear rather than respect for their legitimate properties"* (Drug Enforcement Administration, Last Acts, et al., 2001).

The National Association of Attorneys General (2003b) recognized this joint approach and issued a resolution endorsing a balanced approach to pain management:

> *"…there is a consensus among law enforcement agencies, health care practitioners, and patient advocates that the prevention of drug abuse is an important societal goal that can and should be pursued without hindering proper patient care; and…it is crucial that public health, law enforcement, and government officials continue to develop strategies and methods to prevent the abuse and diversion of prescription drugs, while safeguarding the right of those suffering from severe and chronic pain to continue to have access to appropriate medications"* (p. 1).

In a separate report that same year, the National Association of Attorneys General (2003a) reconfirmed its commitment to balance by stating that:

> *"…the Attorney General should actively promote the concept of balance that legitimate law enforcement goals should be pursued without adversely affecting the provision of quality end-of-life care"* (p. 20).

SECTION VI:
The Imperative to Evaluate Federal and State Policy for Balance

SOME DRUG CONTROL POLICIES HAVE THE POTENTIAL TO IMPEDE THE USE OF OPIOIDS FOR PAIN RELIEF

International and national authorities have called attention to the inadequate treatment of pain and have concluded that this is due in part to statutes and regulations that impede the adequate availability and medical use of opioids.

The International Narcotics Control Board (INCB)[9] observed that the medical need for opiates in the world was not being fully met. In cooperation with the WHO, the INCB (1989) determined that there were a number of reasons for inadequate availability of opiates for pain relief in the world, including unduly restrictive drug control policies:

> *"...the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. The problem may also arise as a result of the manner in which drug control laws and regulations are interpreted or implemented"* (p. 1).
>
> *"...legislators sometimes enact laws which not only deal with the illicit traffic itself, but also impinge on some aspects of licit trade and use, without first having adequately assessed the impact of the new laws on such licit activity. Heightened concern with the possibility of abuse may also lead to the adoption of overly restrictive regulations which have the practical effect of reducing availability for licit purposes"* (p. 15).

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (1990) issued a special report that addressed the obstacles to meeting medical needs for opioids to relieve cancer pain, and concluded that legislative, regulatory, and administrative impediments exist in various countries, leading to underutilization of opioids. More recently, the Council of Europe (2003), WHO HIV/AIDS (2004), the INCB (2005), and the UN ECOSOC (2005a) have all called for governments to identify and address regulatory barriers in the narcotics control policies.

The Institute of Medicine (IOM) (1997, 2001) concluded that there is evidence to support the contention that anti-diversion policies in the U.S. discourage the appropriate use of opioids in pain management. In addition, an expert panel of the National Institutes of Health (NIH) (2002) included *"concern about legal or regulatory sanctions for overuse of opioids"* (p. 13) in a list of impediments to effective symptom management in people diagnosed with cancer. A National Consensus Project on Quality Palliative Care (Arnold, Berger, et al., 2004) identified the need for palliative care programs to be knowledgeable about the legal and regulatory issues surrounding the appropriate prescribing of opioids and other controlled substances.

[9] The International Narcotics Control Board is an independent treaty-based body affiliated with the United Nations that monitors implementation of the Single Convention on Narcotic Drugs of 1961.

The American Pain Society (APS) (Miaskowski, Cleary, et al., 2005) recognized the importance of identifying and addressing state laws and regulations that restrict or overly-regulate the prescribing of opioid analgesics for the treatment of pain, as well as the need to train clinicians about these and other practice issues:

> *"Regulatory barriers, real or perceived, are often cited as one important reason that cancer pain is inadequately treated...some healthcare professionals continue to report concern about regulatory scrutiny, and some are being held accountable for not providing adequate pain management...It remains a high priority to improve state pain-related policies; education both clinicians and regulators about pain management, substance abuse, and improper diversion of controlled substances; and ensure that enforcement and regulatory actions do not interfere with professional practice and patient care"* (p. 7).

Drug Control Policy Should Be Evaluated

Several international and national authorities have called for studies to identify legal and regulatory impediments to the use of opioids for pain relief.

Following a review of the reasons for inadequate cancer pain relief, in cooperation with the WHO, the INCB (1989) communicated with governments throughout the world, asking them to:

> *"...examine the extent to which their health-care systems and laws and regulations permit the use of opiates for medical purposes, identify possible impediments to such use and develop plans of action to facilitate the supply and availability of opiates for all appropriate indications"* (p. 17).

The WHO (1990) recommended that governments review their administrative practices for opioid control with a view to simplification so as not to impede legitimate use of opioids by patients.

The IOM Committee on Opportunities in Drug Abuse Research (1996) recommended:

> *"...additional research on the effects of controlled substance regulations on medical use and scientific research. Specifically, these studies should encompass the impact of such regulations and their enforcement on prescribing practices and patient outcomes in relation to conditions such as pain...[and]... for patients with addictive disorders"* (p. 259).

The IOM Committee on Care at the End of Life (1997) recommended:

> *"...review of restrictive state laws, revision of provisions that deter effective pain relief, and evaluation of the effect of regulatory changes on state medical board policies..." [and] "reform [of] drug prescription laws, burdensome regulations, and state medical board policies and practices that impede effective use of opioids to relieve pain and suffering"* (p. 198, 267).

The IOM Committee on Cancer Control in Low- and Middle-Income Countries (2007) recommended:

> *"Governments should collaborate with national organizations and leaders to identify and remove barriers to ensure that opioid pain medications, as well as other essential palliative care medicines, are available under appropriate control. The INCB and WHO should provide enhanced guidance and support, and assist governments with this task"* (p. 250).

The ACS (Cancer Pain Management Policy Review Group, 2001a) stated:

> *"…additional and sustained efforts are needed to ensure that new barriers are not erected and that adequate pain relief for cancer patients is assured"* (p. 3).

An NIH expert panel (2002) recognized that:

> *"Regulatory barriers need to be revised to maximize convenience, benefit, and compliance…"* (p. 15).

SECTION VII:
The Research Criteria

The criteria used to evaluate the policies are based on the Central Principle of Balance, and are presented in the following two sections: (1) those that identify positive provisions that may enhance pain management, and (2) those that identify negative provisions that may impede pain management. For this evaluation, balanced policy recognizes the legitimacy of controlled substances prescribing and pain management practice, and is operationalized by having policy with a number of positive provisions and few, if any, negative provisions.

Each criterion is elaborated with relevant conclusions and recommendations from international and national expert bodies.

Criteria that identify provisions that may *enhance* pain management

- # 1 Controlled substances are recognized as necessary for public health
- # 2 Pain management is recognized as part of general medical practice
- # 3 Medical use of opioids is recognized as legitimate professional practice
- # 4 Pain management is encouraged
- # 5 Practitioners' concerns about regulatory scrutiny are addressed
- # 6 Prescription amount alone is recognized as insufficient to determine legitimacy of prescribing
- # 7 Physical dependence or analgesic tolerance are *not* confused with "addiction"
- # 8 Other provisions that may enhance pain management
  - Category A: Issues related to healthcare professionals
  - Category B: Issues related to patients
  - Category C: Regulatory or policy issues

Criteria that identify provisions that may *impede* pain management

- # 9 Opioids are considered a treatment of last resort
- #10 Medical use of opioids is implied to be outside legitimate professional practice
- #11 Physical dependence or analgesic tolerance are confused with "addiction"
- #12 Medical decisions are restricted
  - Category A: Restrictions based on patient characteristics
  - Category B: Mandated consultation
  - Category C: Restrictions regarding quantity prescribed or dispensed
  - Category D: Undue prescription limitations
- #13 Length of prescription validity is restricted
- #14 Practitioners are subject to undue prescription requirements
- #15 Other provisions that may impede pain management
- #16 Provisions that are ambiguous
  - Category A: Arbitrary standards for legitimate prescribing
  - Category B: Unclear intent leading to possible misinterpretation
  - Category C: Conflicting or inconsistent policies or provisions

Part A. Criteria to Identify Provisions That May *Enhance* Pain Management

CRITERION #1. CONTROLLED SUBSTANCES ARE RECOGNIZED AS NECESSARY FOR THE PUBLIC HEALTH

According to the Central Principle of Balance, the purpose of controlled substances policies is to prevent the abuse of drugs (including opioids) and also to recognize their important contribution to public health. Controlled substances policies are in addition to, but should not conflict with, the system that regulates the prescribing and dispensing of prescription medications that are approved for human use. This dual purpose of drug control policy should be included in a state's Controlled Substances Act (CSA) (Joranson, 1990b; Joranson & Gilson, 1994; National Conference of Commissioners on Uniform State Laws, 1994).

The INCB (1996) stated that:

> *"Governments should determine whether their national narcotic laws contain elements of the 1961 Convention and the 1972 Protocol that take into account the fact that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and the fact that adequate provision must be made to ensure the availability of narcotic drugs for such purposes and to ensure that administrative responsibility has been established... for the implementation of those laws"* (p. 16).

The WHO (2004) stated that:

> *"No health system in the world offers unlimited access to all medicines. Rational selection of essential medicines is one of the core principles of a national drug policy...It is a global concept which can be applied in any country, in both public and private sectors and at different levels of the health care system"* (p. 3).

The Federal CSA stated that:

> *"Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people"* (Controlled Substances Act, Title 21 §801(1)).

The National Conference of Commissioners on Uniform State Laws (1990) stated that:

> *"Legitimate use of controlled substances is essential for public health and safety, and the availability of these substances must be assured"* (p. 2).

CRITERION #2. PAIN MANAGEMENT IS RECOGNIZED AS PART OF GENERAL MEDICAL PRACTICE

In balanced policy, pain management is a fundamental part of medical practice. The Single Convention places the relief of pain and suffering within the purview of medicine and science (United Nations, 1977); the WHO has recommended that the health professions and all governments adopt an approach for the management of cancer pain that includes the use of opioid analgesics (1986, 2002), and has classified a number of opioid analgesics as Essential Drugs (1998b).

In the U.S., medical practice is regulated at the state level. Therefore, state medical practice laws should recognize that the diagnosis and treatment of pain, including the use of drugs, is a part of ordinary medical practice. The Federation's *Modern Medical Practice Act* (MMPA) for the U.S. is a model statute to guide the development of state medical practice acts. The MMPA defined "practice of medicine" to include:

> *"offering or undertaking to prevent or to diagnose, correct, and/or treat…any disease, illness, pain, wound, fracture, infirmity…"* (Federation of State Medical Boards of the United States Inc., 2000, p. 2).

In addition, the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* adopted by the House of Delegates of the Federation (2004) stated:

> *"…principles of quality medical practice dictate that the people of the State of [name of state] have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain…The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness"* (p. 5).

CRITERION #3. MEDICAL USE OF OPIOIDS IS RECOGNIZED AS LEGITIMATE PROFESSIONAL PRACTICE

This criterion recognizes that a licensed practitioner's use of opioids for pain management is a legitimate medical purpose and is considered to be within the boundaries of professional practice as long as certain basic requirements are met. As a general rule, laws that govern the use of drugs with an abuse liability prohibit uses for other than legitimate medical purposes.

The Single Convention (United Nations, 1977), the INCB (1996), the WHO (1986, 1990, 1996), the U.S. CSA (Controlled Substances Act, Title 21 §801(1)), the Uniform Controlled Substances Act (National Conference of Commissioners on Uniform State Laws, 1994), the DEA (2004), and the FSMB (2004) regard the prescribing of opioids for pain as a legitimate professional practice. In addition, some states have adopted policies stating that legitimate professional practice with controlled substances includes the medical use of opioids for pain management.

The DEA (2004) stated that:

> *"Controlled substances, particularly narcotic analgesics, may be used in the treatment of pain experienced by a patient with a terminal illness or intractable pain. These drugs have legitimate uses and the pharmacist should not hesitate to dispense them when a prescription indicates they are for a legitimate medical purpose"* (p. 55)

The *Model Policy* adopted by the Federation (2004) stated:

> *"The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins...The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment"* (pp. 5-6)

CRITERION #4. PAIN MANAGEMENT IS ENCOURAGED

Policies that regulate professional practice or medications can encourage (or discourage) pain management. Those who make public policy can provide leadership, encouragement, and direction for eliminating the barriers to pain management by adopting positive statements about the importance of controlling pain. It should be noted that there may be unforeseen consequences in adopting policy statements about pain management: depending on the specific language ultimately agreed to, the result may be *increased* restrictions and *increased* practitioner hesitancy to treat pain.

A number of bodies have adopted clear and positive policy statements, including the INCB and the WHO at the international level. In the U.S. a number of expert bodies have done so as well:

The American Pain Society (2005) emphasized that:

> *"Because pain is pervasive in cancer, all healthcare professionals who care for patients at any stage of their illness should know how to assess pain, how to treat it, and when to refer to others with more expertise patients whose pain they are unable to manage"* (p. x)

The IOM (1997) stated that:

> *"Reliable, excellent care at the end of life is an objective that should be supported, not impeded, by public policy"* (p. 206).

The DEA (2004) stated:

> *"It is the position of the DEA that controlled substances should be prescribed and dispensed when there is a legitimate medical need"* (p. 55).

The *Model Policy* adopted by the House of Delegates of the Federation (2004) recommended that:

> *"The Board encourages physicians to view pain management as part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness...Accordingly, this policy has been developed to...encourage better pain management*" (p. 5)

CRITERION #5. PRACTITIONERS' CONCERNS ABOUT REGULATORY SCRUTINY ARE ADDRESSED

Inadequate use of opioids for pain management can stem from many factors. One well-recognized factor is healthcare professionals' concerns that their prescribing practices for pain may be construed to be in violation of drug control or professional practice laws because of misunderstanding about the rational use of opioids. For decades physicians have reported being reluctant to prescribe opioids because of concern about the stress, expense, and consequences of being investigated by licensing agencies or, more recently, law enforcement. These fears have profound implications for practitioners' willingness to consider these medications a viable treatment option and, in turn, hinder their adequate availability for patient pain relief (Hoffmann & Tarzian, 2003; National Conference of Commissioners on Uniform State Laws, 1990; Rich, 2005; Richard & Reidenberg, 2005); such reluctance can be based on excessively strict regulations, the *perception* that regulations or enforcement are excessive, a lack of knowledge about the regulations, or a lack of confidence in the use of opioids. A policy that is balanced and able to overcome these concerns should (1) recognize that a concern about regulatory scrutiny exists, (2) clarify that a physician may prescribe opioids for pain without a risk of disciplinary sanction, and, most importantly, (3) be implemented by the appropriate regulatory bodies.

In support of this criterion at the international level, the INCB has observed that the need for opioids is not being fully met; in cooperation with the WHO, the INCB studied the reasons for inadequate availability of opioids for pain relief in the world.

The INCB (1989) determined that there were a number of reasons for inadequate availability, including that:

> *"the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. The problem may also arise as a result of the manner in which drug control laws and regulations are interpreted or implemented"* (p. 1).

The INCB (1989) further suggested that:

> *"Health professionals... should be able to...[provide opiates]...without unnecessary fear of sanctions for unintended violations...[including]...legal action for technical violations of the law...[that]...may tend to inhibit the prescribing or dispensing of opiates"* (p. 15).

An INCB survey (1996) of impediments to opioid availability reported that:

> *"...reluctance to prescribe or stock opiates owing to concerns about legal sanctions ranked third (47%)"* (p. 4).

As a result, the INCB (1996) requested that all governments in the world:

> *"determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede prescribing, dispensing or needed medical treatment...[and]... communicate with health professionals about the legal requirements for prescribing and dispensing narcotic drugs and...provide an opportunity to discuss mutual concerns"* (pp. 15-16).

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (1990) stated that:

> *"Health care workers may be reluctant to prescribe, stock or dispense opioids if they feel that there is a possibility of their professional licenses being suspended or revoked by the governing authority in cases where large quantities of opioids are provided to an individual, even though the medical need for such drugs can be proved"* (p. 39).

In the U.S., the Federation (2004) *Model Policy* clearly stated that:

> *"...this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage pain management...Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice"* (pp. 5-6).

The American Medical Association House of Delegates (2003) issued a resolution stating that:

> *"...physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain should not be subject to the burdens of excessive regulatory scrutiny, inappropriate disciplinary action, or criminal prosecution. It is the policy of the AMA that state medical societies and boards of medicine develop or adopt mutually acceptable guidelines protecting physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain before seeking the implementation of legislation to provide that protection..."* (p. 1).

CRITERION #6. PRESCRIPTION AMOUNT ALONE IS RECOGNIZED AS INSUFFICIENT TO DETERMINE LEGITIMACY OF PRESCRIBING

This criterion addresses another specific source of concern about regulatory policy: that duration or amount of drug therapy will be used to judge the propriety of prescribing. Outdated views about the "appropriate" use of opioids held that dosing and duration should be limited so as to prevent harm from "excessive" doses or the inevitable onset of "habituation" or "addiction," and that such use of drugs could not be justified in some patient populations. Policies that maintain this outdated concept contradict the Central Principle of Balance by failing to conform to current medical and scientific consensus, and may inadvertently contribute to a restrictive regulatory environment for pain management.

Neither international nor U.S. federal controlled substances policy limits the dose, amount or duration of prescribing. However, some state regulatory policies continue to restrict the number of doses or the duration of treatment. On the other hand, some states have issued policies to clarify that the quantity of medication or the duration of treatment is not sufficient by itself to judge the legitimacy of a practitioner's opioid prescriptions for a pain patient.

In the U.S., this view was recognized by the Food and Drug Administration (FDA):

> *"Once the new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert"* (Federal Register, 1972, p. 16503).

The WHO (1996) clearly supported this position:

> *"Decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, and not by regulation"* (p. 58).

The Federation's (2004) *Model Policy* stated:

> *"The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain..."* (p. 6).

By 2004, the DEA continued to support this view:

> *"The quantity of drug prescribed and frequency of prescriptions filled are not alone indications of fraud or improper prescribing especially if the patient is being treated with opioids for pain management"* (DEA, 2004, p. 82).

CRITERION #7. PHYSICAL DEPENDENCE OR ANALGESIC TOLERANCE ARE *NOT* CONFUSED WITH "ADDICTION"

According to the INCB survey (1996), concern about addiction was the impediment to improving availability and use of opioids most frequently identified by government narcotic control agencies. The use of addiction-related terminology, especially if undefined or defined inaccurately, is fraught with potential for confusing addiction with the physical dependence or tolerance that is common when opioids are used to treat chronic pain (Gilson & Maurer, in press; Gilson & Joranson, 2002; Joranson & Gilson, 2003; Maurer, Gilson, et al., 2008; National Conference of Commissioners on Uniform State Laws, 1990, 1994). Policies that continue to use archaic terminology (e.g., habituation, drug dependence, etc.), which is inconsistent with current medical and scientific knowledge, are considered unbalanced.

It is not necessary for state policy to use terms that identify classes of persons such as "addict" or "habitué" and no modern model acts do so. If such terminology appears in current drug control or professional practice policy, they should either be removed or be defined according to the prevailing medical standard for defining "addiction" (Savage, Joranson, et al., 2003).

Early interpretations of the meaning of addiction are incorrect by today's standards, but may have influenced policy that still exists. A 1941 article in the *Journal of the American Medical Association* revealed the prevailing belief about addiction:

> *"The use of narcotics in the terminal cancer [patient] is to be condemned if it can possibly be avoided. Morphine and terminal cancer are in no way synonymous. Morphine usage is an unpleasant experience to the majority of human subjects because of undesirable side effects. Dominant in the list of these unfortunate effects is addiction"* (Lee, 1941, p. 217).

A 1952 statement from the WHO, the expert body consulted in the development of international drug control policy, confused the critically important distinction between physical and psychological dependence:

> *"There are some drugs, notably morphine and pharmacologically morphine-like substances, whose specific pharmacological action, under individual conditions of time and dose, will always produce compulsive craving, dependence, and addiction in any individual. Addiction will develop sooner in those individuals whose psychological make-up leads them to seek and find escape in the pharmacological action of drugs. Sooner or later there must come a time when the use of the drug cannot be interrupted without significant disturbance, always psychic (psychological) and sometimes physical. With these drugs pharmacological action is paramount, psychological make-up adjuvant. Such drugs cause individual and sociological damage and must be rigidly controlled"* (World Health Organization, 1952, p. 10).

In 1969 WHO replaced the term "addiction" with the term "drug dependence." "Drug dependence" was correctly defined as psychological dependence, with neither physical dependence nor tolerance sufficient to define "drug dependence" (or "addiction"):

> *"Drug dependence. A state, psychic and sometimes also physical, resulting from the interaction between a living organism and a drug, characterized by behavioral and other responses that always include a compulsion to take the drug on a continuous or periodic basis in order to experience its psychic effects, and sometimes to avoid the discomfort of its absence. Tolerance may or may not be present"* (World Health Organization, 1969, p. 6).

The WHO (1996) also clarified correctly that cancer patients who are physically dependent, the manifestation of which would be a withdrawal syndrome if the opioid medication were stopped abruptly, are not considered to be "drug dependent":

> *"Psychological dependence, or 'drug dependence,' is a behavioral pattern characterized by craving for the drug and an overwhelming preoccupation with obtaining it. Undue anxiety about psychological dependence has caused physicians and patients to use inadequate doses of opioids. Wide clinical experience has shown that psychological dependence does not occur in cancer patients as a result of receiving opioids for relief of pain. This is true of both children and adults"* (p. 19).
>
> *"Studies have shown that, while physical dependence and tolerance do occur in patients who take opioids over a long period, psychological dependence is extremely rare. Consequently, the risk of such dependence should not be a factor in deciding whether to use opioids to treat the cancer patient with pain"* (p. 41).
>
> *"Physical dependence, which may develop when opioids are used to treat chronic pain, should not be confused with psychological dependence"* (p. 58).

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (1990) evaluated studies that differentiate the risk of psychological dependence (addiction) from medically prescribed opioids, emphasizing that:

> *"...drug use alone is not the major factor in the development of psychological dependence..."* (p. 37).

Expert national medical and regulatory authorities agreed:

> *"Neither physical dependence nor tolerance should be equated with addiction or substance abuse"* (Institute of Medicine Committee on Care at the End of Life, 1997, p. 193).
>
> *"Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction"* (Federation of State Medical Boards of the United States Inc., 2004, p. 5).
>
> *"Opioid tolerance and physical dependence are expected with long-term opioid treatment and should not be confused with psychological dependence ("addiction"). The misunderstanding of these terms in relation to opioid use contributes to ineffective practices in prescribing, administering, and dispensing opioids for cancer pain management and leads to undertreatment. The presence of opioid tolerance and physical dependence does not equate with 'addiction,' which manifests itself as drug abuse behavior"* (American Pain Society: Miaskowski, Cleary, et al., 2005, p. 55).

Weissman and Haddox (1989) have coined the term "pseudoaddiction." This term has come to characterize a situation in which the pattern of drug-seeking behavior by a pain patient who is receiving inadequate pain management is mistaken by healthcare providers for addictive behavior. The inappropriate perception of pain patients as drug-seekers or persons with addictive disease can result in denial of the opioid prescriptions they need for pain management. As a result, clinical efforts must try to identify instances of "pseudoaddiction" and differentiate them from true addiction.

In 2001, three U.S. national organizations (the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine) collaborated to prepare a consensus document on the use of key terms related to the use of opioids for the treatment of pain. They drew several conclusions and recommended that organizations use the definitions:

"Clear terminology is necessary for effective communication regarding medical issues. Scientists, clinicians, regulators, and the lay public use disparate definitions of terms related to addiction. These disparities contribute to a misunderstanding of the nature of addiction and the risk of addiction, especially in situations in which opioids are used, or are being considered for use, to manage pain. Confusion regarding the treatment of pain results in unnecessary suffering, economic burdens to society, and inappropriate adverse actions against patients and professionals" (p. 1).

"Physical dependence, tolerance, and addiction are discrete and different phenomena that are often confused. Since their clinical implications and management differ markedly, it is important that uniform definitions, based on current scientific and clinical understanding, be established in order to promote better care of patients with pain and other conditions where the use of dependence-producing drugs is appropriate, and to encourage appropriate regulatory policies and enforcement strategies" (American Academy of Pain Medicine, American Pain Society et al., 2001, p. 1).

1. ***Addiction***
   Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.

2. ***Physical Dependence***
   Physical dependence is a state of adaptation that is manifested by a drug class specific syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.

3. ***Tolerance***
   Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time." (American Academy of Pain Medicine, American Pain Society, et al., 2001, p. 2).

The Federation (2004) included these jointly-prepared definitions of Addiction, Physical Dependence, and Tolerance, with slight but non-substantive changes, in their *Model Policy*.

CRITERION #8. OTHER PROVISIONS THAT MAY ENHANCE PAIN MANAGEMENT

This analysis identified several provisions with potential to enhance pain management that were related to the Central Principle of Balance but for which no specific criterion existed. Three categories of policy provisions have the potential to enhance pain management:

Category A: Issues related to healthcare professionals. This category is exemplified by several states recognizing the need for physicians to have flexibility while adhering to state medical board policy, or encouraging multidisciplinary collaboration when treating pain (Strickland, Huskey et al., 2007). In addition, this criterion is used to identify policy language that recognizes that a physician's intentional refusal to treat a patient's pain can be grounds for professional discipline: If pain management is part of quality medical practice, then it follows that inadequate pain management may be substandard practice (Fishman, 2007; Furrow, 2001; Martino, 1998). Policies that extend beyond addressing practitioners' concerns about regulatory scrutiny (identified by Criterion #5), and attempt to provide additional immunity from criminal prosecution, also meet this criterion. Also, some state legislatures design policies to insulate healthcare professionals from criminal liability for their good faith efforts at pain relief when using opioid analgesics, even if the medications are perceived to increase the risk of death; such provisions attempt to protect the physician who uses opioids appropriately.

Category B: Issues related to patients. This category includes provisions specifically aimed at improving pain management for specific groups of at-risk patients. For example, some state policies exempt people with a terminal illness from restrictive prescription requirements (although the restrictive requirements continue to apply to all other patients), or explicitly recognize that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management (Fine & Portenoy, 2007). Also, in some states, patients have the right to request or reject treatment options based on their having received adequate information about pain management and palliative care.

Category C: Regulatory or policy issues. An example of a provision fulfilling this category includes establishing a policy with the clear intent to prevent the abuse or diversion of controlled substances while, at the same time ensuring their availability for legitimate medical and scientific purposes, thereby directly reflecting the Central Principle of Balance. Also, although most laws establishing prescription monitoring programs do not promote Balance or require evaluation of outcomes, some contain statements of Balance or require a report on the program's effectiveness and how it impacts patient care. Finally, many state laws establish policy mechanisms to improve pain management, such as the development of licensing or practice standards for assessing and treating patients' pain.

Part B. Criteria to Identify Provisions That May *Impede* Pain Management

CRITERION #9. OPIOIDS ARE CONSIDERED A TREATMENT OF LAST RESORT

Policies consistent with the Central Principle of Balance recognize the appropriate use of opioid analgesics as part of legitimate medical practice. Today, we know that opioids can be used effectively to relieve chronic pain (Burckhardt, Goldenberg, et al., 2005; Dworkin, O'Connor, et al., 2007; Fishman, 2007; Miaskowski, Cleary, et al., 2005; Simon, Lipman, et al., 2002). However, mistaken beliefs about opioids, based on inaccurate or outdated information, contribute to their underuse for relief of pain. Moreover, a regulatory policy can discourage the medical use of opioids to treat pain, even though the purpose of the policy is to encourage pain management by addressing physicians' concerns about regulatory scrutiny. Some state policies assert that opioids be used *only* after other methods of treatment have failed (Joranson & Gilson, 1997). Although there is no question that non-pharmacologic and non-opioid treatments are valuable, the decision about when to use a particular treatment, including when to use opioids, should be medical and not governmental. State legislators and regulators should avoid promoting an inflexible protocol for the complex and evolving clinical decision-making process concerning the role of opioid therapy.

CRITERION #10. MEDICAL USE OF OPIOIDS IS IMPLIED TO BE OUTSIDE LEGITIMATE PROFESSIONAL PRACTICE

This criterion is the converse of Criterion #2 and Criterion #3, and identifies policy provisions, usually found in Intractable Pain Treatment Acts, that place the medical use of opioids for pain outside the framework of ordinary professional practice, thereby suggesting the practice may not be legitimate. IPTAs grant legal permission and possible disciplinary immunity for practitioners who prescribe opioid analgesics for "intractable pain" under the conditions of the statute. "Intractable pain" is commonly defined in IPTAs as "a pain state…which *in the generally accepted course of medical practice* no relief or cure of the cause of the pain is possible..." (emphasis added). This statement suggests that use of opioids is outside the "generally accepted course of professional practice," which is the reason physicians need immunity for prescribing. Physicians may, therefore, be subject to discipline unless the patient's pain is deemed to satisfy the definition of "intractable pain," and all of the conditions of the IPTA are met.

IPTAs are a product of the time in which they were first created in some states, typically in the late 1980s and early 1990s; many physicians felt that their regulatory authorities viewed opioid use for chronic pain as being outside legitimate medical practice, and they worked with legislators to develop IPTAs to protect this practice from disciplinary action by placing it squarely within legitimate medical practice (Hill, Jr., 1989). A potential consequence of such a policy is that a particular prescribing practice involving controlled substances, which is viewed as outside the IPTA, would be considered a violation of federal and state controlled substances law or regulatory policy. In addition, IPTAs were probably not intended to formalize the use of opioids for pain as being within medical practice only when meeting the IPTA standards. Nevertheless, the resulting IPTA language is not straightforward and appears to be inconsistent with the desirable recognition that pain management, including the use of opioid medications, is, simply stated, part of general medicine and is a legitimate professional practice.

CRITERION #11. PHYSICAL DEPENDENCE OR ANALGESIC TOLERANCE ARE CONFUSED WITH "ADDICTION"

This criterion is the converse of Criterion #7. It is unlawful to use Schedule II opioids for the purpose of maintaining addiction (unless separately registered for this activity pursuant to federal and state law). However, it remains a legitimate medical purpose to prescribe opioids to a patient with an addictive disease if the purpose of prescribing is to relieve pain (DEA, 2004), although such prescribing may require additional expertise and patient monitoring. As explained in Criterion #7, the incorrect use of addiction-related terms still exists in some policies and has the potential to define pain patients as "addicts." According to definitions used in some policies, addiction or drug dependence could be established solely by the presence of physical dependence.

When archaic or confusing policy terminology is applied in practice, it has the potential to stigmatize pain patients and restrict prescribing practices, leading to inadequate pain management. For example, some states still impose restrictions on prescribing to those who "habitually use" controlled substances, although "habitual" is an archaic term discarded by WHO more than 40 years ago (see Criterion #12, Category A). In addition, some states require the practitioner to report "addicts" to a government agency; if physical dependence or analgesic tolerance is interpreted as "addiction," pain patients could be reported even if they do not exhibit compulsive drug use despite harm (see Criterion #14).

CRITERION #12. MEDICAL DECISIONS ARE RESTRICTED

Patient care decisions should be based on medical expertise and individual patient characteristics. In a balanced policy on medical use of opioids, it should be professionals with medical training who make treatment decisions and not the government. Medical practitioners, due to their training and experience, are in a better position than the government to evaluate a patient's needs, make diagnoses, and decide treatment, including the eligibility of patients to receive opioids, choice of medication, and the dose and duration of prescribing.

The WHO (1996) stated:

> *"Decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, and not by regulation"* (p. 58).

The ACS (Cancer Pain Management Policy Review Group, 2001a) declared:

> *"The American Cancer Society strongly supports the primacy of clinical decision-making between patients and health care providers and opposes any efforts that might have an adverse effect on health care providers' willingness and ability to provide pain medication and pain management when treating patients with cancer and other serious or life-threatening illness. The Society encourages the drug enforcement community to work with the health care community and patient advocates to develop a balanced policy toward controlled substances"* (p. 4).

The American Pain Society (2005) recognized that:

> *"State laws and regulations vary considerably, and many restrict or [overly-] regulate the prescription of opioids for the treatment of pain in ways that federal law does not"* (p. 6)

Four categories of policy provisions have the potential to restrict medical decisions and impede patient care:

Category A: Restrictions based on patient characteristics. Some state statutes and regulations limit the physician from prescribing controlled substances to certain patient populations (Gilson & Joranson, 2002). For example, some state policies prohibit or narrowly limit prescribing to the *class* of "addicts." These provisions may pre-date federal policy, which only prohibits physicians from using Schedule II opioid drugs for the *purpose* of maintaining narcotic addiction but not to treat pain in persons who may have an addictive disease (see also Criterion #2 and Criterion #3). For example, such state policies have the potential to create treatment disparities that interfere with pain management in persons with an addictive disease who also have cancer or HIV/AIDS and who need an opioid analgesic for pain. Efforts in some states to correct this problem have resulted in additional and complex language that may have a net effect of being more, rather than less, restrictive. A provision that meets this negative criterion (i.e., one that bars prescribing to certain classes of patients) should be distinguished from a provision that meets Criterion #11, which has the potential to label and stigmatize as "addicts" patients with pain who are using controlled substances and subsequently become tolerant or physically dependent.

Category B: Mandated consultation. There is no question that physicians should seek consultation when needed. However, some state policies, such as IPTAs, *require* the physician to obtain a consultation from a specialist for each intractable pain patient as a means to qualify for immunity from discipline for prescribing opioids to that patient. Such a requirement may be inappropriate if the practitioner is knowledgeable, appears to excessively regulate pain management and the class of patients who have chronic pain, and does not allow for the possibility that the patient may need immediate treatment. Although intended to improve access to pain relief, such policies instead may discourage pain management or limit patient access because of the increased time and administrative burden for the physician, a lack of available consultation resources, as well as the possibility of increased cost for the patient. Also, when a state policy requires a consultation, what is the liability of a physician who prescribes an opioid in the course of treating a patient with pain who does not obtain the consultation?

Category C: Restrictions regarding quantity prescribed or dispensed. This criterion is the converse of Criterion #6. Federal law does not limit the quantity of drug prescribed or dispensed and avoids using quantity or duration to determine the legitimacy of the physician's treatment of the patient. Some state policies limit the amount of Schedule II controlled substances that can be prescribed or dispensed at one time, apparently intending to prevent abuse, diversion, and addiction. Such policies were likely adopted when the prevailing wisdom held that the development of addiction was primarily related to the dose and duration of prescribing. However, the quantity specified in a government policy may not be sufficient to meet the individual medical needs of patients under all legitimately-occurring circumstances, and can result in inadequate treatment of pain.

The *Model Policy* adopted by the Federation (2004) stated:

> *"The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain..."* (p. 6).

Category D: Undue prescription limitations. Some statutes and regulations place additional and unduly strict limits on prescribing or dispensing Schedule II controlled substances for pain management; these conflict with current medical and scientific understanding and are unnecessarily more restrictive than federal controlled substances policy. For example, some states recommend drug holidays as a routine part of prescribing, or appear to disallow off-label prescribing, which is recognized as a legitimate medical practice under federal policy.

In 1975, the FDA clarified its support of off-label prescribing:

> *"Certainly, where a physician uses a drug for a use not in the approved labeling, he has the responsibility to be well informed about the drug and to base such use on a firm scientific rationale or on sound medical evidence, and to maintain adequate medical records of the drug's use and effects, but such usage in the practice of medicine is not in violation of the Federal Food, Drug, and Cosmetic Act"* (Federal Register, 1975, p. 15394).

The FDA has stated:

> *"Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling"* (Food and Drug Administration, 1982, p. 5).
>
> *"Once a drug product has been approved for marketing, a physician may, in treating patients, prescribe the drug for uses not included in the drug's approved labeling"* (Federal Register, 1983, p. 26733).

Finally, in providing guidance to physicians for interpreting product labeling, the *Physician's Desk Reference* (Thomson Healthcare, 2001) stated:

> *"The FDA has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug…The FDA also observes that accepted medical practice includes drug use that is not reflected in approved drug labeling"* (Foreword).

CRITERION #13. LENGTH OF PRESCRIPTION VALIDITY IS RESTRICTED

In balanced drug control policy, efforts to reduce drug diversion do not interfere with availability of medications to the patient. Federal law and most state laws do not establish a period of validity for a controlled substances prescription (i.e., the number of days within which the prescription must be dispensed following its issue). However, some states, such as Hawaii, have limited the period of validity to as little as 3 days, apparently in an effort to reduce "uncashed," although valid, prescriptions as a possible source of diversion. While states can adopt stricter requirements than federal law, unrealistically short validity periods can make it difficult for a patient to obtain medications without having to make extraordinary and sometimes expensive arrangements, especially when travel restrictions, slow mail delivery, or other extenuating circumstances exist. Exceeding a prescription's validity period necessitates issuance of a new

prescription and likely a return visit to the physician. For this evaluation, validity periods of less than two weeks (14 days) are considered potentially restrictive.

CRITERION #14. PRACTITIONERS ARE SUBJECT TO UNDUE PRESCRIPTION REQUIREMENTS

Historically, several states enacted Prescription Monitoring Programs (PMPs) that required the physician to use government-issued prescription forms only when prescribing controlled substances in certain schedules (usually only medications in Schedule II) (see Table 3). Several subsequent studies showed that, after implementation of such programs, the prescribing of those drugs being monitored declined substantially and appeared to have caused an increase in the prescribing of drugs in lower (less restricted) schedules that may be less clinically effective for the patient's condition (Ross-Degnon, Simoni-Wastila, et al., 2004; Simoni-Wastila, Ross-Degnon, et al., 2004; Simoni-Wastila & Tompkins, 2001; Wagner, Soumerai, et al., 2003; Wastila & Bishop, 1996). Reduction in medication prescribing resulting from implementation of a PMP has been interpreted by some enforcement authorities to indicate only a reduction in over-prescribing, and is therefore seen as a positive outcome.

A number of publications have examined the purpose of PMPs and their effects on diversion, medical practice, and patient care (Alliance of States with Prescription Monitoring Programs, 1999; Drug Enforcement Administration & National Alliance for Model State Drug Laws, 2000; Joranson, Carrow, et al., 2002; United States General Accounting Office, 2002, 2004). Representatives of PMPs indicate that such programs are not intended to interfere with medical practice (Alliance of States with Prescription Monitoring Programs, 1999; Drug Enforcement Administration - Office of Diversion Control, 1998), and that precautions are taken to avoid interference. The PMP's purpose is to provide law enforcement and prescribers and dispensers with information on "doctor shoppers," "scammers," and dishonest physicians. Special government-required prescription forms also are said to have the advantage of reducing forgeries.

Some experts have expressed concern that PMP requirements for government forms for Schedule II medications can have a "chilling effect" on physician prescribing because of the implied risk of being investigated for "excessive" or "inappropriate" prescribing by government officials who may not understand medical uses of controlled substances for varying needs of individual patients (Cancer Pain Management Policy Review Group, 2001c; Fishman et al., 2004). Some physicians have reported that they did not obtain the government prescription forms because of the burden of ordering, re-ordering and maintaining security. In some states, it has been shown that over half of all licensed physicians did not have the prescription forms necessary to prescribe the selected controlled substances, so that a physician would not be able to prescribe an opioid for severe pain when necessary.

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (1990) has addressed the issue of special government prescription forms:

> *"Record-keeping and authorization requirements should not be such that, for all practical purposes, they eliminate the availability of opioids for medical purposes. Multiple-copy prescription programmes are cited as means of reducing careless prescribing and 'multiple doctoring' (patients registering with several medical practitioners in order to obtain several prescriptions for the same, or similar, drugs). There is some justification for thus* (sic)*, but the extent to which these programmes restrict or inhibit the prescribing of opioids to patients who need them should also be questioned"* (p. 39).

The World Health Assembly (2005) echoed this approach, recognizing the need:

> *"to ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Narcotics Control Board and subject to an efficient monitoring and control system"* (p. 3)

In the U.S., the National Association of Attorneys General (2003b), while acknowledging the public health implications of both drug abuse and inadequate pain management, encouraged states to:

> *"Ensure that…programs or strategies implemented to reduce abuse of prescription pain medication are designed with attention to their potential impact on the legitimate use of prescription drugs"* (p. 2)

All states with PMPs currently utilize Electronic Data Transfer (EDT) systems in conjunction with their program (Brushwood, 2003), either alone or in combination with a government-required form or a security form (both for multiple schedules of drugs). Although there are few sources of definitive data on this subject, it is considered an improvement to eliminate the requirement that physicians use a government-issued prescription form for a single drug schedule, and that EDT alone is less intrusive to physicians' prescribing and can help to identify errant prescribers and doctor shoppers (Alliance of State Pain Initiatives, 2008; National Alliance for Model State Drug Laws, 2002). Several states recently have chosen to require that physicians use prescription forms that are printed on security paper when prescribing any controlled substance, but such forms are not government-issued.

These recent PMP developments support the requirements of the National All Schedules Prescription Electronic Reporting Act (NASPER) (Public Health and Welfare, Title 42 § 280g-3), which was signed into federal law in 2005 and provides formula grants to states for creating a PMP that covers prescribing of medications in at least Schedules II-IV. States can still adopt PMPs that do not meet NASPER Act requirements, but they would not receive federal government funding to do so. NASPER provides a mandate for the Secretary of Health and Human Services to evaluate the safety and efficacy of each program created under the Act, but the outcome measures are left undefined.

This negative criterion is satisfied when a state's PMP law requires the physician to use a government-issued prescription form for Schedule II controlled substances only, because of the stigmatization of this important class of medications and because research has shown that the use of government issued special forms can impede appropriate prescribing. PMPs that utilize EDT technology to monitor multiple schedules of controlled substances, either with a regular prescription form or with a security form, did not satisfy this criterion at this time due to a lack of published studies examining their effect on prescribing.

This criterion also applies to special requirements that healthcare professionals must follow only for patients receiving prescriptions for Schedule II controlled substances. Examples include requirements that pharmacists verify the need for dose increases before dispensing a prescription, and that practitioners report to a government agency the names of patients receiving Schedule II medications. When practitioners are required to report to a government agency either patients receiving opioids or "addicts," this could affect pain patients in states where physical dependence or analgesic tolerance are considered syonymous with "addiction."

CRITERION #15. OTHER PROVISIONS THAT MAY IMPEDE PAIN MANAGEMENT

This analysis identified several additional provisions that are related to the Central Principle of Balance and that have the potential to impede pain relief, but were not sufficiently specific to fulfill an individual criterion. For example, a state's law permits pharmacists to refuse to fill a prescription if potential harm is anticipated, even if such a determination is based solely on the quantity of medication prescribed. In another state, the Department of Justice can assign a physician to examine the records of any patient prescribed a Schedule II or III medication, or who is a "habitual user." If implemented, such a requirement could subject both physicians and patients to undue scrutiny and seriously disrupt legitimate prescribing and patient care.

CRITERION #16. PROVISIONS THAT ARE AMBIGUOUS

This analysis identified several provisions having the potential to impede pain management due to ambiguity of language. The test we used to identify ambiguous provisions was whether the language would be clear to a person, professional or lay, who only reads the words of the provision to understand its meaning.

Three categories of policy provisions have the potential to create ambiguity:

Category A: Arbitrary standards for legitimate prescribing. This category is exemplified primarily by several states establishing a standard for unprofessional conduct (for physicians, osteopaths, or pharmacists) as the prescribing, dispensing, administering, or distribution of a prescription drug or controlled substance in an "excessive" manner or in "amounts greater than medically necessary." Left undefined, these terms may contribute to practitioners' uncertainty about what standard determines the legitimacy of a particular prescribing practice and who sets that standard.

Category B: Unclear intent leading to possible misinterpretation. This category includes vague statutory or regulatory language that can make it difficult for practitioners to understand the explicit meaning of the policy provision or the specific actions that the policy requires. A prevalent example of this category is language that seems to suggest that a physician cannot prescribe opioids as a treatment of first choice, regardless of pain severity or other clinical considerations that would justify their appropriate initial use (see rationale for this in Criterion #9). Such provisions typically occur in intractable pain treatment policies, which have been created to provide immunity to physicians who prescribe controlled substances for "intractable pain." "Intractable pain" is typically defined as a pain state in which no relief or cure in possible or none has been found after reasonable efforts; it seems logical, therefore, that "reasonable efforts" do not include the use of controlled substances. As a result, the policy provides immunity for prescribing opioids to patients with a history of failed treatments, but would exclude opioid treatment for patients who present initially with severe pain.

Category C: Conflicting or inconsistent policies or provisions. This category includes provisions in a state's pain policies that appear to contradict or do not conform to other policy provisions, thereby creating conflicting requirements. Such inconsistencies can occur between different policies (typically statutes and the regulations that implement them), or even for provisions in the same policies. A characteristic set of provisions, contained in many IPTAs, recognize that it is legitimate medical practice to prescribe opioids to treat pain in patients with an addictive disease, but at the same time provides no authority to physicians who prescribe to persons using controlled substances for non-therapeutic purposes; this establishes a seemingly contradictory treatment standard. In addition, there are many instances where statutory language does not conform to the language created in regulations to implement the statute.

SECTION VIII:
Results – Profiles of Federal and State Pain Profiles

Alabama
Alaska
Arizona
Arkansas
California
Colorado
Connecticut
Delaware
District of Columbia
Florida
Georgia
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Washington
West Virginia
Wisconsin
Wyoming

Federal

U.S.

FEDERAL

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 21. Food and Drugs

- PUBLIC HEALTH AND WELFARE
  Title 42. The Public Health and Welfare

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 21. Food and Drugs

- PUBLIC HEALTH
  Title 42. The Public Health

- PUBLIC WELFARE
  Title 45. Public Welfare

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- VETERANS' BENEFITS
  Title 38. Veterans' Benefits

US

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act	●							
Public Health and Welfare								●
REGULATIONS								
Food and Drugs								●
Public Health							●	●
Public Welfare								●
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Veteran's Benefits								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management								
Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Public Health and Welfare			●					
REGULATIONS								
Food and Drugs								●
Public Health[1]								
Public Welfare[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Veteran's Benefits[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

FEDERAL

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION1:*
Controlled substances are necessary for public health

21 USCS § 801

§ 801. Congressional findings and declarations: controlled substances

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

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21 USCS § 801a

§ 801a. Congressional findings and declarations: psychotropic substances

The Congress makes the following findings and declarations:

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(3) In implementing the Convention on Psychotropic Substances, the Congress intends that, consistent with the obligations of the United States under the Convention, control of psychotropic substances in the United States should be accomplished within the framework of the procedures and criteria for classification of substances provided in the Comprehensive Drug Abuse Prevention and Control Act of 1970. This will insure that (A) the availability of psychotropic substances to manufacturers, distributors, dispensers, and researchers for useful and legitimate medical and scientific purposes will not be unduly restricted; (B) nothing in the Convention will interfere with bona fide research activities; and (C) nothing in the Convention will interfere with ethical medical practice in this country as determined by the Secretary of Health, Education, and Welfare [Secretary of Health and Human Services] on the basis of a consensus of the views of the American medical and scientific community.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

FEDERAL

STATUTES

Public Health and Welfare

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

42 USCS § 201

§ 201. Definitions

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(q) The term "drug dependent person" means a person who is using a controlled substance (as defined in section 102 of the Controlled Substances Act [*21 USCS § 802*]) and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.

42 USCS § 280g-3

§ 280g-3. Controlled substance monitoring program

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(j) Studies and reports.
(1) Implementation report.
(A) In general. Not later than 180 days after the date of enactment of this section [enacted Aug. 11, 2005], the Secretary, based on a review of existing State controlled substance monitoring programs and other relevant information, shall determine whether the implementation of such programs has had a substantial negative impact on--
(i) patient access to treatment, including therapy for pain or controlled substance abuse;
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(2) Progress report. Not later than 3 years after the date on which funds are first appropriated under this section, the Secretary shall--
(A) complete a study that--
(i) determines the progress of States in establishing and implementing controlled substance monitoring programs under this section;
(ii) provides an analysis of the extent to which the operation of controlled substance monitoring programs have reduced inappropriate use, abuse, or diversion of controlled substances or affected patient access to appropriate pain care in States operating such programs;
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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes mechanisms to determine whether the prescription monitoring programs impede the appropriate medical use of controlled substances.

42 USCS § 14402

§ 14402. Restriction on use of Federal funds under health care programs

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(b) Construction and treatment of certain services. Nothing in subsection (a), or in any other provision of this Act (or in any amendment made by this Act), shall be construed to apply to or to affect any limitation relating to--
(1) the withholding or withdrawing of medical treatment or medical care;
(2) the withholding or withdrawing of nutrition or hydration;
(3) abortion; or
(4) the use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason.
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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians that there is an important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

FEDERAL

CODE OF FEDERAL REGULATIONS

Food and Drugs

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Does this imply that opioids are a last resort?

21 CFR 1306.07

§ 1306.07 Administering or dispensing of narcotic drugs.

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(c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

FEDERAL

CODE OF FEDERAL REGULATIONS

Food and Drugs

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: These provisions were evaluated only for federal policies because the federal, not state, government regulates the use of controlled substances due to their abuse liability, thereby setting the standard in this area of medical practice.

21 CFR 1306.11

§ 1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with § 1304.04(h) of this chapter.
(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to § 1306.07.
(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.
(d) In the case of an emergency situation, as defined by the Secretary in § 290.10 of this title, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner,... prepared in accordance with § 1306.05 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (e) and it shall be maintained in accordance with § 1304.04(h) of this chapter.
(f) A prescription prepared in accordance with § 1306.05 written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (f) and it shall be maintained in accordance with § 1304.04(h).
(g) A prescription prepared in accordance with § 1306.05 written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with § 1304.04(h).

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21 CFR 1306.13

§ 1306.13 Partial filling of prescriptions.

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

CODE OF FEDERAL REGULATIONS

Public Health

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

42 CFR 8.2

§ 8.2 Definitions.

The following definitions apply to this part:

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Opiate addiction is defined as a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opiates despite significant opiate-induced problems. Opiate dependence is characterized by repeated self-administration that usually results in opiate tolerance, withdrawal symptoms, and compulsive drug-taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

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42 CFR 411.15

§ 411.15 Particular services excluded from coverage.

The following services are excluded from coverage:

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(q) Assisted suicide. Any health care service used for the purpose of causing, or assisting to cause, the death of any individual. This does not pertain to the withholding or withdrawing of medical treatment or care, nutrition or hydration or to the provision of a service for the purpose of alleviating pain or discomfort, even if the use may increase the risk of death, so long as the service is not furnished for the specific purpose of causing death.

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42 CFR 483.315

§ 483.315 Specification of resident assessment instrument.

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(e) Minimum data set (MDS). The MDS includes assessment in the following areas:

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(10) Disease diagnoses and health conditions, which includes active medical diagnoses, physical problems, pain assessment, and stability of condition.

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(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (Minimum Data Set) to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians that there is an important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

CODE OF FEDERAL REGULATIONS

Public Welfare

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

45 CFR 1643.4

§ 1643.4 Applicability.

(a) Nothing in § 1643.3 shall be interpreted to apply to:

(1) The withholding or withdrawing of medical treatment or medical care;

(2) The withholding or withdrawing of nutrition or hydration;

(3) Abortion;

(4) The use of items, goods, benefits, or services furnished for purposes relating to the alleviation of pain or discomfort even if they may increase the risk of death, unless they are furnished for the purpose of causing or assisting in causing death;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians that there is an important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

FEDERAL

STATUTES

Veteran's Benefits

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

38 USCS § 7327

§ 7327. Centers for research, education, and clinical activities on complex multi-trauma associated with combat injuries

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(c) Requirements for centers. To be designated as a center under this section, a facility shall--
(1) be a regional lead center for the care of traumatic brain injury;
(2) be located at a tertiary care medical center and have on-site availability of primary and subspecialty medical services relating to complex multi-trauma;
(3) have, or have the capacity to develop, the capability of managing impairments associated with combat injuries;
(4) be affiliated with a school of medicine;
(5) have, or have experience with, participation in clinical research trials;
(6) provide amputation care and rehabilitation;
(7) have pain management programs;
(8) provide comprehensive brain injury rehabilitation; and
(9) provide comprehensive general rehabilitation.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (pain management programs) for VA centers to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

AL

ALABAMA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 20. Food, Drugs, and Cosmetics; Chapter 2. Controlled Substances

- MEDICAL PRACTICE ACT
  Title 34. Professions and Businesses; Chapter 24. Physicians and Other Practitioners of Healing Arts;
  Article 3. Physicians and Osteopaths
  Article 8. Licensing and Registration of Physicians and Osteopaths

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 34. Professions and Businesses; Chapter 23. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Alabama Uniform Controlled Substances Regulations; Chapter 680-X-3

- MEDICAL BOARD REGULATIONS
  Alabama Board of Medical Examiners; Chapter 540-X

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Alabama Board of Pharmacy; Chapter 680-X

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- IN-HOME HOSPICE SERVICES
  State Health Planning and Development Agency; Alabama State Health Plan 2004-2007; Chapter 410-2-3: Specialty Services

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act		●						
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board		●	●	●	●	●	●	●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
In-Home Hospice Services								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management								
Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
In-Home Hospice Services[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

ALABAMA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Code of Ala. § 20-2-2

§ 20-2-2. Definitions

When used in this chapter, the following words and phrases shall have the following meanings, respectively, unless the context clearly indicates otherwise:

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(20) Practitioner.

a. A physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.

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(+) *CRITERION 3: Opioids are part of professional practice*

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Code of Ala. § 34-24-50

§ 34-24-50. "Practice of medicine or osteopathy" defined

The "practice of medicine or osteopathy" means:

(1) To diagnose, treat, correct, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;

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(+) *CRITERION 2: Pain management is part of medical practice*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

§ 540-X-4-.08

540-X-4-.08 Guidelines for the Use of Controlled Substances for the Treatment of Pain

(1) Preamble.

(a) The Board recognizes that principles of quality medical practice dictate that the people of the State of Alabama have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as to reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the *U.S. Agency for Health Care and Research Clinical Practice Guidelines* for a sound approach to the management of acute pain (Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.) and cancer-related pain (Jacox A, Carr DB, Payne R. et al. Management of Cancer Pain. Clinical Practice Guideline No. 9. AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research, U.S. Department of Health and Human Resources, Public Health Service. March 1994). The medical management of pain should be based upon current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board is obligated under the laws of the State of Alabama to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use.

(e) Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

[CONTINUED]

(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs - including any improvement in functioning - and recognizing that some types of pain cannot be completely relieved.

(g) The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(2) Guidelines. The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(c) Informed Consent and Agreement for Treatment. The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities including

1. urine/serum medication levels screening when requested
2. number and frequency of all prescription refills; and
3. reasons for which drug therapy may be discontinued (i.e. violation of agreement)

(d) Periodic Review. At reasonable intervals based upon the individual circumstance of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should re-evaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

(e) Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

(f) Medical Records. The physician should keep accurate and complete records to include:

1. the medical history and physical examination;
2. diagnostic, therapeutic and laboratory results;
3. evaluations and consultations;
4. treatment objectives;
5. discussion of risks and benefits;
6. treatments;
7. medications (including date, type, dosage, and quantity prescribed);
8. instructions and agreements; and
9. periodic reviews.

Records should remain current, and be maintained in an accessible manner, and readily available for review.

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state, and comply with applicable federal and state regulations. Physicians are referred to *the Physicians Manual of the U.S. Drug Enforcement Administration* and applicable state regulations for rules governing controlled substances.

(3) Definitions. For the purposes of these guidelines, the following terms are defined as follows:

(a) Acute pain. Acute pain is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

(b) Addiction. Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(c) Analgesic Tolerance. Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(d) Chronic Pain. A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

(e) Pain. An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(f) Physical Dependence. Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(g) Pseudoaddiction. Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) Substance Abuse. Substance abuse is the use of any substance(s) for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.

(i) Tolerance. Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

In-Home Hospice Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (care plan) for in-home hospices to ensure that pain management is an essential part of patient care.

Ala. Admin. Code r. 410-2-3-.10

410-2-3-.10 In-Home Hospice Services.

(1) Discussion

(a) Hospice care is a choice you make to enhance life for a dying person. Hospice focuses on caring, not curing and, in most cases, care is provided in the patient's home. Hospice care also is provided in freestanding hospice centers, hospitals, and nursing homes and other long-term care facilities. Hospice services are available to patients of any age, religion, race, or illness. Hospice care is covered under Medicare, Medicaid, most private insurance plans, HMOs, and other managed care organizations.

(b) Members of the hospice staff make regular visits to assess the patient and provide additional care or other services. Hospice staff is on-call 24 hours a day, seven days a week. The hospice team develops a care plan that meets each patient's individual needs for pain management and symptom control. Emotional and spiritual support is also provided to meet the patient's needs and wishes as well as that of the family.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

AK

ALASKA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 11. Criminal Law; Chapter 71. Controlled Substances

  Title 17. Food and Drugs; Chapter 30. Controlled Substances

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 8. Businesses and Professions; Chapter 64. Medicine

- PHARMACY PRACTICE ACT
  Title 8. Businesses and Professions; Chapter 80. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  No policy found

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 12. Professional and Vocational Regulations; Part 1. Boards and Commissions Subject to Centralized Licensing; Chapter 40. State Medical Board

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 12. Professional and Vocational Regulations; Part 1. Boards and Commissions Subject to Centralized Licensing; Chapter 52. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HOSPICE AGENCIES
  Title 7. Health and Social Services; Part 1. Administration; Chapter 12. Facilities and Local Units; Article 7. Hospice Agencies

AK

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Pharmacy Practice Act			●					
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[2]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Agencies								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

AK

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[2]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Agencies[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Alaska Stat. § 11.71.900

Sec. 11.71.900. Definitions

In this chapter, unless the context clearly requires otherwise,

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(19) "practitioner" means

(A) a physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer or use in teaching or chemical analysis a controlled substance in the course of professional practice or research in the state;

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(+) *CRITERION 3:* *Opioids are part of professional practice*

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Alaska Stat. § 08.80.480

Sec. 08.80.480. Definitions

In this chapter, unless the context otherwise requires,

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(28) "practitioner" means an individual currently licensed, registered, or otherwise authorized by the jurisdiction in which the individual practices to prescribe and administer drugs in the course of professional practice;

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(+) *CRITERION 3:* *Opioids are part of professional practice*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospice Agencies

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (inpatient care) for hospices to ensure that pain management is an essential part of patient care.

7 Alaska Admin. Code 12.316

7 AAC 12.316. Scope of service: full-service hospice agency

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(d) The hospice agency shall arrange for short-term inpatient care if home care is not feasible for pain control, symptom management, and respite purposes. The agency shall ensure that any short-term inpatient care is provided in a licensed facility that is most appropriate to meet the client's needs.

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7 Alaska Admin. Code 12.338

7 AAC 12.338. Hiring, orientation, and training

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(e) A full-service hospice agency shall provide an educational program that offers a comprehensive overview of hospice philosophy and hospice care. The agency shall provide a minimum of 18 hours of education within a one-year period for each direct service provider delivering hospice care. The four hours of orientation training required under (b) of this section may be counted as part of the 18 hours required under this subsection. The educational program must include at least the following subjects:

(1) hospice philosophy;

(2) family dynamics;

(3) pain and symptom management;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (educational program) for hospices to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

AZ

ARIZONA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 36. Public Health and Safety; Chapter 27. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 32. Professions and Occupations; Chapter 13. Medicine and Surgery

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Title 32. Professions and Occupations; Chapter 17. Osteopathic Physicians and Surgeons

- PHARMACY PRACTICE ACT
  Title 32. Professions and Occupations; Chapter 18. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Title 4. Professions and Occupations; Chapter 23. Board of Pharmacy; Article 10. Uniform Controlled Substances and Drug Offenses

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 4. Professions and Occupations; Chapter 16. Arizona Medical Board

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Title 4. Professions and Occupations; Chapter 22. Board of Osteopathic Examiners in Medicine and Surgery

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 4. Professions and Occupations; Chapter 23. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Arizona Medical Board. *Guidelines for the Use of Controlled Substances for the Treatment of Chronic Pain*. Agency Substantive Policy Statement #7. Adopted: June 2003.

- OSTEOPATHIC BOARD GUIDELINE
  Arizona Board of Osteopathic Examiners in Medicine and Surgery. *Guidelines: The Prescribing of Controlled Substances for the Treatment of Pain Management*. Adopted: January 22, 2000.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HEALTH SERVICES

  Title 9. Health Services; Chapter 10. Department of Health Services: Health Care Institutions: Licensing; Article 2. Hospitals

  Title 9. Health Services; Chapter 20. Department of Health Services: Behavioral Health Service Agencies: Licensure; Article 10. Opioid Treatment

AZ

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act			●					
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
Osteopathic Board Guideline		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Health Services: Hospitals								●
Health Services: Opioid Treatment								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
Osteopathic Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Health Services: Hospitals[1]								
Health Services: Opioid Treatment[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

ARIZONA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

A.R.S. § 36-2501

§ 36-2501. Definitions

A. In this chapter, unless the context otherwise requires:

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5. "Drug dependent person" means a person who is using a controlled substance and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuing basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.

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(-) *CRITERION 11:* *Physical dependence or analgesic tolerance confused with "addiction"*

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

A.R.S. § 32-1901

§ 32-1901. Definitions

In this chapter, unless the context otherwise requires:

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70. "Practitioner" means any physician, dentist, veterinarian, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research in this state, or any pharmacy, hospital or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research in this state.

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(+) *CRITERION 3:* *Opioids are part of professional practice*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

The Guidelines for Treatment of Chronic Pain

Introduction

The diagnosis and treatment of pain is integral to the practice of medicine. The Arizona Medical Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain because of terminal illness.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery, and in the treatment of chronic pain, whether due to cancer or non-cancer origins.

The following guidelines demonstrate the Board's desire to encourage physicians to administer controlled substances in the course of treating pain without fear of disciplinary action from this Board when such treatment is provided with the accepted community standard of care.

Policy for the Treatment of Chronic Pain

Section I: Preamble

The Board recognizes that access to the highest quality medical care includes access to effective and appropriate pain relief. Appropriate up-to-date treatment modalities improve the quality of life for patients who suffer from chronic pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain.

When investigating allegations of inappropriate pain management, the Board gathers all relevant medical records, statements from the complainant and physician and has the information reviewed by a physician(s) experienced in pain management. The Board refers to current clinical practice guidelines and expert analysis when reviewing cases involving pain management. The Board judges the validity of the physician's treatment of the patient based on all the information, not just quantity and duration of the medication administration.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for chronic pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must document chronic pain associated with an objective pain generator and/or a recognized chronic pain syndrome. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of chronic pain.

The Laws of the State of Arizona mandate that the Board protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Diversion of controlled substances should be a concern of every health professional, but efforts to stop diversion should not interfere with prescribing opioids when appropriate for chronic pain management. Attention to patterns of prescription requests and inappropriate drug seeking behavior can decrease the risk of diversion and abuse. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (using opinions from physicians experienced in pain management) to review allegations against physicians for inappropriate pain management.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) ***CRITERION 7:*** ***Physical dependence or analgesic tolerance are not confused with "addiction"***

(CONTINUED)

The chronic pain management goal is to address the patient's pain along with other aspects of the patient's functioning, including physical, psychological, social and work-related factors. When managing chronic pain, the physician should consider current clinical knowledge, evidence-based clinical practice, medical research and the use of pharmacologic and multidisciplinary non-pharmacologic modalities. The physician should adjust the quantity and frequency of doses according to the intensity and duration of the pain. Physicians must recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

Section II: Guidelines
The following guidelines apply to the physician's treatment of chronic pain, including the long-term use of controlled substances:

Evaluation of the Chronic Pain Patient – Evaluation should initially include a pain history and assessment of the impact of pain on the patient, a directed physical examination, a review of previous diagnostic studies, a review of previous interventions, a drug history, and an assessment of coexisting diseases or conditions.

Treatment Plan – Treatment planning should be tailored to both the individual and the presenting problem. Consideration should be given to different treatment modalities, such as formal pain rehabilitation program, the use of behavioral strategies, the use of non-invasive techniques, or the use of medications, depending upon the physical and psychosocial impairment related to the pain. An opioid trial should not be initiated in the absence of a complete assessment of the chronic pain complaint.

Informed Consent – The physician must discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. This discussion should include the risks of addiction/abuse, not alleviating all pain, and treatment alternatives including the effects of no treatment.

Agreement for Treatment – There are circumstances in which the use of a documented verbal or written agreement between physician and patient outlining patient responsibilities may be necessary for safe and responsible opioid prescribing. Such an agreement should include:

- o urine/serum medication levels and baseline screening when requested;
- o number and frequency of all prescription refills;
- o reasons for which drug therapy may be discontinued (e.g., violation of agreement)
- o requirement that the patient receive all controlled substance prescriptions from one physician and one pharmacy whenever possible.

Periodic Review – Review of treatment efficacy should occur periodically to assess any new information about the etiology of the pain or the patient's state of health, the functional status of the patient, continued analgesia, opioid side effects, quality of life, and indications of medication misuse. Periodic re-examination is warranted to assess the nature of the pain complaint and to ensure that opioid therapy is still indicated. Attention should be given to the possibility of a decrease in global function or quality of life because of opioid use.

Consultation – Consultation with a specialist in pain medicine or with a psychologist may be warranted, depending on the expertise of the practitioner and the complexity of the presenting problem. The management of chronic pain in patients with a history of addiction or a co-morbid psychiatric disorder requires special consideration, but does not necessarily contraindicate the use of opioids.

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(+) ***CRITERION 8:*** ***Other provisions that may enhance pain management***

CATEGORY A: ***Issues related to healthcare professionals***

COMMENT: Recognizes that the goals of pain treatment should include improvements in patient functioning and quality of life.

(+) ***CRITERION 8:*** ***Other provisions that may enhance pain management***

CATEGORY B: ***Issues related to patients***

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Medical Records – The physician must keep accurate, legible and complete records that provide sufficient information for another practitioner to assume continuity of the patient's care. These records should contain at a minimum the following:

1. The medical history and physical examination,
2. Diagnostic, therapeutic and laboratory results that support the diagnosis,
3. Evaluations and consultations,
4. Treatment objectives,
5. Discussion of risks and benefits,
6. Documented verbal and/or written informed consent,
7. Treatments,
8. Medications (including date, type, dosage and quantity prescribed),
9. Instructions and agreements, and
10. Periodic reviews.

The physician must maintain current records in an easily accessible manner, and the records must be readily available for review.

Termination from Medical Practice
Circumstances may arise which lead the prescribing physician to terminate the treating physician/patient relationship. In such cases, the physician has a medical and ethical responsibility to make an effort to ensure that the patient does not undergo uncontrolled, abrupt withdrawal from the prescribed controlled substance. This can be accomplished by tapering the medication, arranging for inpatient detoxification, or providing continued care and prescription(s) to cover a realistic, limited period during which the patient has the opportunity to find a new treating physician and/or obtain admittance to an opioid detoxification program.

Compliance With Controlled Substances Laws and Regulations – To prescribe, dispense or administer controlled substances, the physician must be licensed in the State and comply with applicable federal and State regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing controlled substances as well as applicable State regulations.

Section III: Definitions
For the purpose of these guidelines, the following terms are defined as follows:

Acute Pain – Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction – Addiction is a primary, chronic, neurobiological disease, with genetic psychosocial and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain – Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain – An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence – Physical dependence is a state of adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Pseudoaddiction – The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse – Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance – Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

ARIZONA

OTHER GOVERNMENTAL POLICY

Osteopathic Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

ARIZONA BOARD OF OSTEOPATHIC EXAMINERS IN MEDICINE AND SURGERY

GUIDELINES: THE PRESCRIBING OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN MANAGEMENT

INTRODUCTION:
The Arizona State Board of Osteopathic Examiners in Medicine and Surgery recognizes that Principles of quality medical practice dictate that the people of the State Of Arizona have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain.

The Board encourages physicians to view effective pain management as part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for those patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain relief as well as statutory requirements for Prescribing controlled substances.

Physicians should not fear disciplinary action from the Board or other state regulatory or Enforcement agencies for Prescribing, dispensing, or administering controlled substances, Including opioid analgesics in the usual course of professional practice. The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a Legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or If based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state and/or federal law.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on the available documentation. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define the complete or best practice, but rather to communicate what the Board considers to be with in the boundaries of professional practice.

PURPOSE:
The purpose of these guidelines regarding the prescribing of controlled substances for the treatment of pain is to establish criteria to be considered by the Board in consideration of allegations of unprofessional conduct. The Board's objective is for these Guidelines to recognize but to not interfere with the medical use of controlled substances for pain relief, while continuing to address the issue of prescribing that may contribute to drug abuse and diversion. These guidelines are general recommendations. Each case involving the prescription of controlled substances for pain management will be judged on all factors related to that patient. These guidelines were created to provide the Board and the Licensed osteopathic medical community a basis in which to provide quality medical care to the citizens of the State of Arizona.

Guidelines:
The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control.

1. Pain Assessment:

A. Medical History

A comprehensive history should include a review of pertinent lab and diagnostic test that have already been performed. The initial evaluation of the pain complaint should include characteristics such as intensity, character, frequency, location, duration, and precipitating and relieving factors, underlying or co-existing diseases or conditions.

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(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Osteopathic Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

It should also include a thorough analgesic medication history, including current and previous prescription medications, over-the-counter medications, natural remedies and illicit drug use.

It should also include an evaluation of physical function. This should focus on pain associated disabilities, including activities of daily living.

B. Psycho-social Assessment

Evaluation should also include assessment of the patient's mood with particular concern regarding anxiety or depression. The physician should assess whether the patient understands the diagnosis. One should also evaluate the patient's expectations about pain relief and pain management methods. The patient may have reservations about the use of controlled substances. The physician should question the patient about their coping mechanisms for pain. This also includes assessment of the patient's social networks, including any dysfunctional family relationships.

C. Physical Exam

Physical exams should focus on the neuromuscular system, search for neurological impairment, weakness, hyperalgesia, allodynia, or parathesias.

One should assess the musculoskeletal system with attention to the palpation of tenderness, Inflammation, deformity, trigger points, and physical function.

2. Treatment Plan:

A. Pain Relief
A treatment plan should be developed for the management of chronic pain. Consideration should also be given to different treatment modalities, such as a formal pain rehabilitation program, the use of behavioral strategies, the use of non-invasive techniques, or the use of medications. The assessment of pain should occur, not only during the initial exam, but also after each new reportive pain, at the appropriate intervals, after each pharmacological intervention and at regular intervals during treatment.

B. Improved Physical Functioning

A quantitative assessment of pain should be recorded by the use of a standard pain scale and pain log. Patients with chronic pain and their caregivers should be instructed on the use of the pain log with regular intervals for pain intensity, medication use, response to treatment, and associated activities.

A qualitative assessment of the treatment plan should include the evaluation of the patient's ability to function productively in society.

3. Informed Consent:

Advise the chronic pain patient or guardian of the risks and the benefits of the use of controlled substances as well as alternatives to that treatment. They should be counseled on the importance of regular visits, the impact of recreational drug use, avoiding the use of multiple pharmacies and physicians for prescriptions and taking medication as directed. A contract should be signed outlining the patient's responsibilities, if appropriate.

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OTHER GOVERNMENTAL POLICY

Osteopathic Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

4. On-going Assessment:

Patients with chronic pain should be re-assessed regularly. The frequency of follow-up should be a function of the pain syndrome and potential for adverse effects of treatment. The physician may consider discontinuing the use or modifying medications if the patient is experiencing side effects that are not tolerable, if clinical improvement does not occur, or if the physician notes non –compliance. The clinician should watch for signs of narcotic use for inappropriate indications like anxiety or depression. Requests for early refills should prompt an evaluation of tolerance to the medication, progression of disease or inappropriate behavioral factors.

5. Consultation and Referral – Optimal Treatment requires a team approach

Psychiatrists, psychologists, pain management specialists are available and should be part of the treatment team specifically in the more complex patient.

6. Documentation:

Documentation is essential for supporting the evaluation. The clinician should include the reason for prescribing controlled substances. The clinician should also document the overall pain management treatment plan, any consultations received, and a periodic review of the status of the patient. The clinician should also include medications and treatments including the date, type, dosage and quantity prescribed.

7. Medical Record – in accordance with A.R.S.§ 32-1800 (2) and A.R.S. § 12-2291(4)

Physician should develop and maintain complete records to include:

Medical history and physical examination
Diagnostic, therapeutic, and lab results;
Evaluations and consultations;
Treatment objectives;
Discussion of risks and benefits;
Treatment;
Medication (include date, type, dose and quantity)
Instructions and agreements; and
Periodic reviews

Records should be accessible and ready for review.

COMPLIANCE WITH LAWS AND REGULATIONS:

Treating physician must possess a valid and current license to practice medicine in the State of Arizona.

A. Possess a Valid and current controlled substances drug enforcement registration for the schedules being prescribed.

B. If drugs are dispensed from the office, the physician must comply with the Arizona State Statutes.

C. If controlled substances are provided for detoxification, the physician should comply with the Arizona State Statutes.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Osteopathic Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

Definitions

For the purpose of these guidelines, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to an adverse chemical, thermal, mechanical or neurological stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction
Addiction is a neurobehavioral syndrome with genetic and environmental influences that result in psychological dependence on the use of substances for the psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(+) ***CRITERION 7:*** ***Physical dependence or analgesic tolerance are not confused with "addiction"***

Analgesic Tolerance
Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does equate with addiction.

Chronic Pain
A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with long term incurable or intractable medical condition or disease.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence
Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself does not equate with addiction.

Pseudo-addiction
Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

ARIZONA

REGULATIONS

Health Services: Hospitals

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (documentation in medical records) for hospitals to ensure that pain management is an essential part of patient care.

A.A.C. § R9-10-217

R9-10-217. Pharmaceutical Services

An administrator shall require that:

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14. If pain medication is administered to a patient, documentation in the patient's medical record includes:

a. An assessment of the patient's pain before administering the medication; and

b. The effect of the pain medication administered;

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REGULATIONS

Health Services: Opioid Treatment

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

A.A.C. § R9-20-1002

R9-20-1002. Administration

A program sponsor shall ensure that:

1. The program sponsor designates a physician to serve as medical director and to have authority over all medical aspects of opioid treatment;

2. Written policies and procedures are developed, implemented, complied with, and maintained at the agency and include:

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g. A requirement that a client who is physiologically dependent as a result of chronic pain receives consultation with or a referral for consultation with a medical practitioner who specializes in chronic pain;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written policies and procedures) for OTP staff to refer opioid-maintained patients who have chronic pain for treatment of their pain.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 5. Criminal Offenses; Subtitle 6. Offenses Against Public Health, Safety, or Welfare; Chapter 64. Controlled Substances

  Title 20. Public Health and Welfare; Subtitle 4. Food, Drugs, and Cosmetics; Chapter 64. Alcohol and Drug Abuse; Subchapter 2. Uniform Narcotic Drug Act

- MEDICAL PRACTICE ACT *(No provisions found)*
  Title 17. Professions, Occupations, and Businesses; Subtitle 3. Medical Professions; Chapter 95. Physicians and Surgeons

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Title 17. Professions, Occupations, and Businesses; Subtitle 3. Medical Professions; Chapter 95. Physicians and Surgeons; Subchapter 7. Treatment of Chronic Intractable Pain

- OSTEOPATHIC PRACTICE ACT *(No provisions found)*
  Title 17. Professions, Occupations, and Businesses; Subtitle 3. Medical Professions; Chapter 91. Osteopaths

- PHARMACY PRACTICE ACT *(No provisions found)*
  Title 17. Professions, Occupations, and Businesses; Subtitle 3. Medical Professions; Chapter 92. Pharmacists and Pharmacies

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  007. Department of Health; 07. Pharmacy Services and Drug Control (Bureau of Health Resources)

- MEDICAL BOARD REGULATIONS
  060. State Medical Board

- OSTEOPATHIC BOARD REGULATIONS
  No policy found

- PHARMACY BOARD REGULATIONS *(No provisions found)*
  070. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HOMICIDE
  Title 5. Criminal Offenses; Subtitle 2. Offenses Against the Person; Chapter 10. Homicide

- HEALTH FACILITY SERVICES
  007. Department of Health; 05. Health Facility Services

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Intractable Pain Treatment Act		●	●	●	●	●		●
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances			●					
Medical Board		●	●					●
Osteopathic Board[2]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Homicide								●
Health Facility Services								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Intractable Pain Treatment Act				●				●
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances[1]								
Medical Board								●
Osteopathic Board[2]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Homicide[1]								
Health Facility Services[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

A.C.A. § 5-64-101

§ 5-64-101. Definitions

As used in this chapter:

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(21) "Practitioner" means:

(A) A physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state;

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(+) *CRITERION 3: Opioids are part of professional practice*

STATUTES

Uniform Narcotic Drug Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Ark. Stat. Ann. § 20-64-207

§ 20-64-207. Professional use of narcotic drugs

(1) Physicians and Dentists. A physician or a dentist, in good faith and in the course of his professional practice only, may prescribe, administer, and dispense narcotic drugs, or he may cause the same to be administered by a nurse or intern under his direction and supervision.

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(+) *CRITERION 3: Opioids are part of professional practice*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

A.C.A. § 17-95-701 – § 17-95-707

§ 17-95-701. Title

This subchapter shall be known and may be cited as the "Chronic Intractable Pain Treatment Act".

§ 17-95-702. Findings

The General Assembly finds that:

(1) Pain management plays an important role in good medical practice;

(2) Physicians should recognize the need to make pain relief accessible to all patients with chronic intractable pain; and

(3) Physicians should view pain management as a regular part of their medical practice for all patients with chronic intractable pain.

§ 17-95-703. Definitions

As used in this subchapter:

(1) "Board" means the Arkansas State Medical Board;

(2) "Chronic intractable pain" means a pain state for which the cause of the pain cannot be removed or otherwise treated and for which no relief or cure has been found after reasonable efforts by a physician;

(3) (A) "Dangerous or controlled drugs" means drugs used for pain relief, including, but not limited to:

(i) Opioids; and

(ii) Other drugs classified under schedules II, III, IV, or V by the United States Food and Drug Administration.

(B) "Dangerous or controlled drugs" does not include any substance the prescription of which is illegal under federal law;

(4) "Disciplinary action" means any remedial or punitive sanctions imposed on a licensed physician by the board;

(5) "Patient" means a person seeking medical diagnosis and treatment; and

(6) "Physician" means a licensee of the Arkansas State Medical Board.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 4:*
Pain management is encouraged

(+) *CRITERION 2:*
Pain management is part of medical practice

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B
Unclear intent leading to possible misinterpretation

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

[CONTINUED]

§ 17-95-704. Arkansas State Medical Board -- Treatment -- Prohibitions

(a) (1) A physician shall not be subject to disciplinary action by the Arkansas State Medical Board solely for prescribing dangerous or controlled drugs for the relief of chronic intractable pain.

(2) (A) (i) Any allegation of improper prescribing determined to require a board hearing shall be referred to the Pain Management Review Committee before any board hearing or action.

(ii) (a) However, in exceptional limited substantive instances requiring immediate action to protect the public health, an emergency action under § 25-15-211(c) may be implemented.

(b) The implementation of an emergency action under § 25-15-211(c) shall in no way be used by the board to circumvent, void, supplant, or otherwise limit the role of the committee as provided in this subchapter.

(B) The board shall provide the committee all necessary documentation for the review process in a timely manner.

(3) The board shall direct the committee to use the criteria under subsections (d) and (e) of this section to review a physician's conduct in regard to prescribing, administering, ordering, or dispensing pain medications and other drugs necessary to treat chronic intractable pain.

(4) (A) If the board determines that an allegation or a question regarding a physician's prescribing does not justify a board hearing, in lieu of a board hearing, the board may refer a physician to the committee for review and recommendations to the board.

(B) The review and recommendations under subdivision (a)(4)(A) of this section shall not adversely affect the physician's license or licensure status.

(b) The board shall:

(1) Make reasonable efforts to notify health care providers under its jurisdiction of the existence of this subchapter;

(2) Inform any health care provider licensed by the board and investigated regarding the provider's practices in the management of pain of the existence of this subchapter; and

(3) (A) In a disciplinary hearing, present opinion evidence from a full-time active practice physician in direct patient care who is knowledgeable in pain management.

(B) The physician has the right to present testimony from a full-time active practice physician in direct patient care who is knowledgeable in pain management.

(c) (1) In lieu of a finding of gross and ignorant malpractice, the board after a hearing may incrementally impose sanctions as follows:

(A) Monitor prescribing habits of the physician not to exceed six (6) months;

(B) Require the physician to voluntarily surrender his or her United States Drug Enforcement Agency license to the board for a specified period of time not to exceed three (3) months;

(C) Suspend the physician's license, stay the suspension, and require monitoring of prescribing habits;

(D) Revoke the physician's license, stay revocation, and require monitoring of the physician's prescribing habits for a specified time; and

(E) Revoke the physician's license for serious violations of statutes and regulations.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (Pain Management Review Committee) to review allegations of improper prescribing against physicians for treating intractable pain before disciplinary determinations are made.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to communicate to practitioners about immunity from board discipline for pain management prescribing practices.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (using opinions from physicians involved in direct care of patients with pain) to decide allegations against physicians for treating intractable pain.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

(2) With a finding of severe violation of statutes and regulations, the board may initially impose the more severe sanctions.

(3) At any level of sanction, the board may require continuing medical education hours in proper prescribing habits.

(d) Based upon evaluation and management of a patient's individual needs, a physician may:

(1) Treat a patient who develops chronic intractable pain with a dangerous or controlled drug to relieve the patient's pain;

(2) Continue to treat the patient for as long as the pain persists;

(3) Treat the pain by managing it with dangerous or controlled drugs in amounts or combinations that may not be appropriate for treating another medical condition;

(4) Administer large doses of dangerous or controlled drugs for pain management if the benefit of relief outweighs the risk of the large dose; and

(5) Administer a large dose of a dangerous or controlled drug even if its use may increase the risk of death if the purpose is not to cause or assist in a patient's death.

(e) A physician may not:

(1) Prescribe or administer dangerous or controlled drugs intended to manage chronic intractable pain to treat a patient for chemical dependency on drugs or controlled substances;

(2) Prescribe or administer dangerous or controlled drugs to a person the physician knows to be using drugs for nontherapeutic purposes;

(3) Prescribe or administer dangerous or controlled drugs to a person for other than legitimate medical purposes; or

(4) (A) Cause or assist in causing the suicide, euthanasia, or mercy killing of any individual.

(B) However, causing or assisting in causing the suicide, euthanasia, or mercy killing of any individual does not include prescribing, dispensing, or administering medical treatment for the purpose of alleviating pain or discomfort even if that use may increase the risk of death so long as the treatment is not furnished for the purpose of causing or assisting in causing the death of the individual.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (Pain Management Review Committee) to review allegations of improper prescribing against physicians for treating intractable pain based on the individual clinical needs of the patient.

[CONTINUED]

§ 17-95-705. Pain Management Review Committee -- Membership -- Duties

(a) There is created the Pain Management Review Committee, appointed by the Arkansas State Medical Board.

(b) The committee shall consist of five (5) members who are full-time active physicians in direct patient care, two (2) of whom may be board-certified pain management specialists and three (3) of whom may be physicians with significant pain management in their practices or with a degree in pharmacy, appointed by the board from a list provided by the Arkansas Osteopathic Medical Association, the Arkansas Medical Society, and the Arkansas Pain Society.

(c) The committee shall:

(1) Have committee representation from the Arkansas Osteopathic Medical Association, the Arkansas Medical Society, and the Arkansas Pain Society to develop guidelines for investigations of complaints regarding conduct in violation of this subchapter;

(2) Review complaints on an individual patient-needs basis regarding physicians treating chronic intractable pain in violation of this subchapter; and

(3) (A) Provide an objective critique to the board for board determination in a timely manner and if so determined, before the board's disciplinary hearing.

(B) In order to ensure a fair, impartial, and objective board hearing, no board member shall be:

(i) Present while the committee reviews allegations of improper prescribing; or

(ii) Involved in any way in the committee's deliberations.

§ 17-95-706. Scope

This subchapter does not condone, authorize, or approve mercy killing or euthanasia, and no treatment authorized by this subchapter may be used for mercy killing or euthanasia.

§ 17-95-707. Immunity -- Criminal prosecution

No physician shall be subject to criminal prosecution for prescribing or administering controlled substances under appropriate criteria in the course of treatment of a person for chronic intractable pain.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (immunity) to protect physicians treating intractable pain from criminal prosecution.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

ARKANSAS

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

007 07 CARR 009

009 Rules and Regulations Pertaining to Controlled Substances

SECTION 1. REGISTRATION

Every Practitioner as defined as follows shall obtain a registration from the Federal Drug Enforcement Administration, Department of Justice unless exempted by Law.

A. A physician, podiatric physician, osteopathic physician, dentist, veterinarian, optometrist, scientific investigator, researcher, mid-level practitioner, or other persons licensed, registered, or otherwise permitted to prescribe, dispense, distribute, administer or conduct research with respect to controlled substances in the course of professional practice or research in Arkansas:

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(+) *CRITERION 3:*
Opioids are part of professional practice

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

060 00 CARR 001

001 Arkansas Medical Practices Regulations

REGULATION NO. 2

The Arkansas Medical Practices Act authorizes the Arkansas State Medical Board to revoke or suspend the license issued by the Board to practice medicine if the holder thereof has been found guilty of grossly negligent or ignorant malpractice.
"Malpractice" includes any professional misconduct, unreasonable lack of skill or fidelity in professional duties, evil practice, or illegal or immoral conduct in the practice of medicine and surgery.
It shall include, among other things, but not limited to:
1. Violation of laws, regulations, and procedures governing payment to physicians for medical services for eligible public assistance recipients and/or other third party payment programs.
2. Participation in any plan, agreement, or arrangement which compromises the quality or extent of professional medical services or facilities at the expense of the public health, safety, and welfare.
3. Practicing fraud, deceit, or misrepresentation in the practice of medicine.
4. The prescribing of excessive amounts of controlled substances to a patient including the writing of an excessive number of prescriptions for an addicting or potentially harmful drug to a patient.
5. The prescribing of Schedule II controlled substances by a physician for his own use or for the use of his immediate family.
6. *The treatment of pain with dangerous drugs and controlled substances is a legitimate medical purpose when done in the usual course of medical practice. If the provisions as set out below in this Resolution are met, and if all drug treatment is properly documented, the Board will consider such practices as prescribing in a therapeutic manner, and prescribing and practicing medicine in a manner consistent with public health and welfare.

[CONTINUED ON NEXT PAGE]

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: "Excessive" implies there is a limit, but the limit is not specified and who determines the limit?

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

However, a physician who prescribes **narcotic agents Schedule 2, 3, 4, and 5, excluding Schedule 4 Propoxyphene products and to include the schedule drugs Talwin, Stadol, and Nubain, on a long term basis (more than six (6) months) for a patient with pain not associated with malignant or terminal illness will be considered exhibiting gross negligence or ignorant malpractice unless he or she has complied with the following:

a. The physician will keep accurate records to include the medical history, physical examination, other evaluations and consultations, treatment plan objective, informed consent noted in the patient record, treatment, medications given, agreements with the patient and periodic reviews.

b. The physician will periodically review the course of schedule drug treatment of the patient and any new information about etiology of the pain. If the patient has not improved, the physician should assess the appropriateness of continued prescribing of scheduled medications or dangerous drugs, or trial of other modalities.

c. The physician will obtain written informed consent from those patients he or she is concerned may abuse controlled substances and discuss the risks and benefits of the use of controlled substances with the patient, his or her guardian, or authorized representatives.

d. The physician will be licensed appropriately in Arkansas and have a valid controlled substance registration and comply with the Federal and State regulations for the issuing of controlled substances and prescriptions, more especially the regulations as set forth in 21 Code of Federal Regulations Section 1300, et sequence.

7. A licensed physician engaging in sexual contact, sexual relations or romantic relationship with a patient concurrent with the physician-patient relationship; or a licensed physician engaging in the same conduct with a former patient, if the physician uses or exploits trust, knowledge, emotions or influence derived from the previous professional relationship, shows a lack of fidelity of professional duties and immoral conduct, thus exhibiting gross negligence and ignorant malpractice. A patient's consent to, initiation of, or participation in sexual relationship or conduct with a physician does not change the nature of the conduct nor the prohibition.

8. **Requiring minimum standards for establishing physician/patient relationships. A physician exhibits gross negligence if he provides and/or recommends any form of treatment, including prescribing legend drugs, without first establishing a proper physician/patient relationship.

A. For purposes of this regulation, a proper physician/patient relationship, at a minimum requires that:

1. The physician performs a history and physical examination of the patient adequate to establish a diagnosis and identify underlying conditions and/or contraindications to the treatment recommended/provided, OR personally knows the patient and the patient's general health status through an "ongoing" personal or professional relationship, AND THAT

2. Appropriate follow-up be provided, when necessary, at medically necessary intervals.

B. For the purposes of this regulation, a proper physician/patient relationship is deemed to exist in the following situations:

1. When treatment is provided in consultation with, or upon referral by, another physician who has an ongoing relationship with the patient, and who has agreed to supervise the patient's treatment, including follow up care and the use of any prescribed medications.

2. On-call or cross-coverage situations.

C. Exceptions -- Recognizing a physician's duty to adhere to the applicable standard of care, the following situations are herby excluded from the requirement of this regulation:

1. Emergency situations where the life or health of the patient is in danger or imminent danger.

2. Simply providing information of a generic nature not meant to be specific to an individual patient.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

060 00 CARR 001

001 Arkansas Medical Practices Regulations

REGULATION NO. 19. PAIN MANAGEMENT PROGRAMS

A. Physicians operating a pain management program for specific syndromes...that is headache, low back pain, pain associated with malignancies, or temporomandibular joint dysfunctions...are expected to meet the standards set forth in this section or in fact be in violation of the Medical Practice Act by exhibiting gross negligence or ignorant malpractice.

B. Definitions:

1. Chronic Pain Syndrome: Any set of verbal and/or nonverbal behaviors that: (1) involves the complaint of enduring pain, (2) differs significantly from a person's premorbid status, (3) has not responded to previous appropriate medical and/or surgical treatment, and (4) interferes with a person's physical, psychological and social and/or vocational functioning.

2. Chronic Pain Management Program provides coordinated, goal-oriented, interdisciplinary team services to reduce pain, improving functioning, and decrease the dependence on the health care system of persons with chronic pain syndrome.

C. The following standards apply to both inpatient and outpatient programs and the physician should conform to the same.

1. There should be medical supervision of physician prescribed services.

2. A licensee should obtain a history and conduct a physical examination prior to or immediately following admission of a person to the Chronic Pain Management Program.

3. At the time of admission to the program, the patient and the physician should enter into a written contract stating the following:

a. The presenting problems of the person served.

b. The goals and expected benefits of admission.

c. The initial estimated time frame for goal accomplishment.

d. Services needed.

[CONTINUED ON NEXT PAGE]

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

[CONTINUED]

D. In order to provide a safe pain program, the scope and intensity of medical services should relate to the medical care needs of the person served. The treating physician of the patient should be available for medical services. Services for the patient in a Chronic Pain Management Program can be provided by a coordinated interdisciplinary team of professionals other than physicians. The members of the core team, though each may not serve every person should include:

a. A Physician.

b. A clinical psychologist or psychiatrist.

c. An occupational therapist.

d. A physical therapist.

e. A rehabilitation nurse.

E. A physician managing a Chronic Pain Management Program to a patient should meet the following criteria:

1. Three years experience in the interdisciplinary management of persons with chronic pain.

2. Participation in active education on pain management at a local or national level.

3. Board certification in a medical specialty or completion of training sufficient to qualify for examinations by members of the American Board of Medical Specialties.

4. Two years experience in the medical direction of an interdisciplinary Chronic Pain Program or at least six (6) months of pain fellowship in an interdisciplinary Chronic Pain Program.

The Physician must have completed and maintained at least one (1) of the following:

5. Attendance at one (1) meeting per year of a regional and national pain society.

6. Presentation of an abstract to a regional national pain society.

7. Publication on a pain topic in a peer review journal.

8. Membership in a pain society at a regional or national level.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Homicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Ark. Stat. Ann. § 5-10-106

§ 5-10-106. Physician-assisted suicide

(a) (1) As used in this section, "physician-assisted suicide" means a physician or health care provider participating in a medical procedure or knowingly prescribing any drug, compound, or substance for the express purpose of assisting a patient to intentionally end the patient's life.

(2) However, "physician-assisted suicide" does not apply to a person participating in the execution of a person sentenced by a court to death by lethal injection.

(b) It is unlawful for any physician or health care provider to commit the offense of physician-assisted suicide by:

(1) Prescribing any drug, compound, or substance to a patient with the express purpose of assisting the patient to intentionally end the patient's life; or

(2) Assisting in any medical procedure for the express purpose of assisting a patient to intentionally end the patient's life.

(c) Upon conviction, any physician or health care provider violating subsection (b) of this section is guilty of a Class C felony.

(d) Nothing in this section prohibits a:

(1) Physician or health care provider from carrying out an advanced directive or living will; or

(2) Physician from prescribing any drug, compound, or substance for the specific purpose of pain relief.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Health Facility Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

007 05 CARR 007

007 Rules and Regulations for Hospice in Arkansas

PREFACE

These rules and regulations have been prepared for the purpose of establishing a criterion for minimum standards for the certification, operation and maintenance of hospices in Arkansas that is consistent with current trends in patient care practices. By necessity they are of a regulatory nature but are considered to be practical minimal design and operational standards for these facilities. These standards are not static and are subject to periodic revisions in the future as new knowledge and changes in patient care trends become apparent. However, it is expected that facilities will exceed these minimum requirements and that they will not be dependent upon future revisions in these standards as a necessary prerequisite for improved services. Hospices have a strong moral responsibility for providing optimum patient care and treatment for the terminally ill and their families.

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SHORT-TERM INPATIENT CARE

Inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in licensed facilities, as stated below:

(a) Inpatient care for symptom control. Inpatient care for pain control and symptom management must be provided in one of the following:

(1) A hospice that meets the requirements for providing inpatient care directly as specified in the section, "Free Standing Hospices Providing Inpatient Care Directly".

(2) A hospital or a Skilled Nursing Facility (SNF) that also meets the requirements specified for nursing service and patient areas. (See paragraphs (a) twenty-four (24) hour nursing services, and (f) patient areas, under "Freestanding Hospices Providing Inpatient Care Directly".)

(b) Inpatient care for respite purposes. Inpatient care for respite purposes must be provided by one of the following:

(1) A provider specified in paragraph (a) of this section.

(2) An Intermediate Care Facility (ICF) that also meets the requirements specified under "Free Standing Hospices Providing Inpatient Care Directly" paragraphs (a) and (f) regarding twenty-four (24) hour nursing service and patient areas.

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(+) *CRITERION 8: Other provisions that may enhance pain management*

CATEGORY C: Regulatory or policy issues

COMMENT: Establishes a responsibility for healthcare facilities to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

CA

CALIFORNIA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Health and Safety Code; Division 10. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Business and Professions Code; Division 2. Healing Arts; Chapter 5. Medicine

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Business and Professions Code; Division 2. Healing Arts; Chapter 5. Medicine; Section 2241.5

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Business and Professions Code
  Appendix; II. Osteopathic Act
  Division 2. Healing Arts; Chapter 5. Medicine
  Article 4.5 Osteopathic Requirements for Licensure;
  Article 21. Provisions Applicable to Osteopathic Physicians and Surgeons

- PHARMACY PRACTICE ACT
  Business and Professions Code; Division 2. Healing Arts; Chapter 9. Pharmacy

- PAIN PATIENT'S BILL OF RIGHTS
  Health and Safety Code; Division 106. Personal Health Care; Part 4.5

- EFFECT ON INTRACTABLE PAIN TREATMENT ACT; BILL OF RIGHTS
  Health and Safety Code; Division 106. Personal Health Care; Part 4.5

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) *(No provisions found)*
  Title 16. Professional and Vocational Regulations; Division 17. California State Board of Pharmacy; *Article 6. Dangerous Drugs*

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 16. Professional and Vocational Regulations; Division 13. Medical Board of California

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Title 16. Professional and Vocational Regulations; Division 16. Osteopathic Medical Board of California

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 16. Professional and Vocational Regulations; Division 17. California State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT

  California Medical Board. "A Statement by the Medical Board." *Action Report*. Vol. 50, pp. 4-5. July 1994.

- MEDICAL BOARD GUIDELINE

  California Medical Board. "Guideline for Prescribing Controlled Substances for Intractable Pain." *Action Report*. Vol. 87, pp. 1, 4-6. October 2003. Adopted: August 2, 2003.

- PHARMACY BOARD POLICY STATEMENT

  California Pharmacy Board. "Dispensing Controlled Substances for Pain." *Health Notes - Pain Management.* Vol. 1, No. 1. 1996.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- REPORTS OF INJURIES

  Penal Code; Part 4. Prevention of Crimes and Apprehension of Criminals; Title 1. Investigation and Control of Crimes and Criminals; Chapter 2. Control of Crimes and Criminals; Article 2. Reports of Injuries

- HEALTH FACILITY LICENSING

  Health and Safety Code; Division 2. Licensing Provisions; Chapter 2. Health Facilities; Article 1. General

- HOSPICE SERVICES

  Title 28. Managed Health Care; Division 1. The Department of Managed Health Care; Chapter 2. Health Care Service Plans; Article 8. Self-Policing Procedures

CA

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					●
Medical Practice Act					●			●
Intractable Pain Treatment Act		●	●		●			●
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Pain Patient's Bill of Rights		●		●				●
Effect on IPTA; Bill of Rights								●
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement		●	●	●	●	●	●	●
Medical Board Guideline		●	●	●	●	●		●
Pharmacy Board Policy Statement			●	●		●	●	
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Reports of Injuries								●
Health Facility Licensing				●				●
Hospice Services								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

CA

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act							●	
Medical Practice Act[1]								
Intractable Pain Treatment Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act								●
Pain Patient's Bill of Rights[1]								
Effect on IPTA; Bill of Rights								●
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement[1]								
Medical Board Guideline[1]								
Pharmacy Board Policy Statement[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Reports of Injuries[1]								
Health and Safety Code[1]								
Hospice Services[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Cal Health & Saf Code § 11156

§ 11156. Prohibited prescription, or dispensation to, addict or other user; Exception

(a) Except as provided in *Section 2241 of the Business and Professions Code*, no person shall prescribe for, or administer, or dispense a controlled substance to, an addict, or to any person representing himself or herself as such, except as permitted by this division.

(b)

(1) For purposes of this section, "addict" means a person whose actions are characterized by craving in combination with one or more of the following:

(A) Impaired control over drug use.

(B) Compulsive use.

(C) Continued use despite harm.

(2) Notwithstanding paragraph (1), a person whose drug-seeking behavior is primarily due to the inadequate control of pain is not an addict within the meaning of this section.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Within a context of prescribing to patients with a prior history or current status of addiction, clarifies for practitioners that there is an important distinction between addiction and pseudoaddiction.

Cal Health & Saf Code § 11159.2

§ 11159.2. Prescriptions for controlled substances for terminally ill patients

(a) Notwithstanding any other provision of law, a prescription for a controlled substance for use by a patient who has a terminal illness may be written on a prescription form that does not meet the requirements of Section 11162.1 if the prescription meets the following requirements:

(1) Contain the information specified in subdivision (a) of Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(c) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exemption of these patients from special prescription requirements nevertheless continues those requirements for all other patients.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

Cal Health & Saf Code § 11210

§ 11210. Permitted prescribing, furnishing, or administering controlled substances by practitioners

A physician, surgeon, dentist, veterinarian, naturopathic doctor acting pursuant to Section 3640.7 of the Business and *Professions Code*, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or naturopathic doctor acting within the scope of *Section 3640.5 of the Business and Professions Code*, or an optometrist acting within the scope of *Section 3041 of the Business and Professions Code* may prescribe for, furnish to, or administer controlled substances to his or her patient when the patient is suffering from a disease, ailment, injury, or infirmities attendant upon old age, other than addiction to a controlled substance.

Cal Health & Saf Code § 11453

§ 11453. Department physician; Interviews and reports; Violation

The Department of Justice may employ a physician to interview and examine any patient for whom any controlled substance classified in Schedule I, II, or III has been prescribed or to whom any such controlled substance has been furnished or administered, or who is an habitual user of such a controlled substance, or who has a previous addiction record to a substance listed as a controlled substance classified in Schedule I, II, or III.

The patient shall submit to the interview and examination and shall not in any manner hinder or impede it.

The physician employed by the Department of Justice to conduct the interview and examination shall report the results of the examination and interview to the department.

The physician so employed may testify in any action brought under this division or in any administrative hearing conducted under the Medical Practice Act or the Osteopathic Act and his or her testimony is not privileged.

Every person who violates any provision of this section is guilty of a misdemeanor.

(-) *CRITERION 15:*
Other provisions that may impede pain management

COMMENT: Authorizing a Department of Justice-assigned physician to examine any California patient who is prescribed a controlled substance, who may be a "habitual user," or who has an "addiction record," and allows a misdemeanor charge to be brought against a patient for not submitting, appears arbitrary, falls well outside the accepted framework of law regarding controlled substances, medical practice and patient confidentiality, and if implemented could subject patients to undue scrutiny and seriously disrupt legitimate medical practice and patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Cal Bus & Prof Code § 2025

§ 2025. Pain management guidelines

The board through its regular mailing shall notify all licensees of the existence of pain management guidelines published by the Agency for Health Care Policy and Research of the Public Health Service within the United States Department of Health and Human Services, and shall provide the published guidelines to licensees upon request.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to communicate to practitioners about existing pain management standards.

Cal Bus & Prof Code § 2089

§ 2089. Proof of completion of medical curriculum; Curriculum requirements

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(b) The curriculum for all applicants shall provide for adequate instruction in the following subjects:

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Pain management and end-of-life care.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory medical curriculum) to provide physicians information/education about pain management and end-of-life care.

Cal Bus & Prof Code § 2190.5

§ 2190.5. Mandatory continuing education course in pain management and treatment of terminally ill and dying patients; Deadline for completion of course; Exemptions; Application

(a) All physicians and surgeons shall complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients. For the purposes of this section, this course shall be a one-time requirement of 12 credit hours within the required minimum established by regulation, to be completed by December 31, 2006. All physicians and surgeons licensed on and after January 1, 2002, shall complete this requirement within four years of their initial license or by their second renewal date, whichever occurs first. The board may verify completion of this requirement on the renewal application form.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management and palliative care.

Cal Bus & Prof Code § 2196.2

§ 2196.2. Information on pain management

The board shall periodically develop and disseminate information and educational material regarding pain management techniques and procedures to each licensed physician and surgeon and to each general acute care hospital in this state. The board shall consult with the State Department of Health Services in developing the materials to be distributed pursuant to this section.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to communicate to practitioners about acceptable practices governing pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Cal Bus & Prof Code § 2220.05

§ 2220.05. Prioritization of allegations

(a) In order to ensure that its resources are maximized for the protection of the public, the Medical Board of California shall prioritize its investigative and prosecutorial resources to ensure that physicians and surgeons representing the greatest threat of harm are identified and disciplined expeditiously. Cases involving any of the following allegations shall be handled on a priority basis, as follows, with the highest priority being given to cases in the first paragraph:

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(3) Repeated acts of clearly excessive prescribing, furnishing, or administering of controlled substances, or repeated acts of prescribing, dispensing, or furnishing of controlled substances without a good faith prior examination of the patient and medical reason therefore. However, in no event shall a physician and surgeon prescribing, furnishing, or administering controlled substances for intractable pain consistent with lawful prescribing, including, but not limited to, Sections 725, 2241.5, and 2241.6 of this code and *Sections 11159.2 and 124961 of the Health and Safety Code*, be prosecuted for excessive prescribing and prompt review of the applicability of these provisions shall be made in any complaint that may implicate these provisions.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Cal Bus & Prof Code § 2241

§ 2241. Furnishing drugs to addict

(a) A physician and surgeon may prescribe, dispense, or administer prescription drugs, including prescription controlled substances, to an addict under his or her treatment for a purpose other than maintenance on, or detoxification from, prescription drugs or controlled substances.

(b) A physician and surgeon may prescribe, dispense, or administer prescription drugs or prescription controlled substances to an addict for purposes of maintenance on, or detoxification from, prescription drugs or controlled substances only as set forth in subdivision (c) or in *Sections 11215, 11217, 11217.5, 11218, 11219, and 11220 of the Health and Safety Code*. Nothing in this subdivision shall authorize a physician and surgeon to prescribe, dispense, or administer dangerous drugs or controlled substances to a person he or she knows or reasonably believes is using or will use the drugs or substances for a nonmedical purpose.

(c) Notwithstanding subdivision (a), prescription drugs or controlled substances may also be administered or applied by a physician and surgeon, or by a registered nurse acting under his or her instruction and supervision, under the following circumstances:

(1) Emergency treatment of a patient whose addiction is complicated by the presence of incurable disease, acute accident, illness, or injury, or the infirmities attendant upon age.

(2) Treatment of addicts in state-licensed institutions where the patient is kept under restraint and control, or in city or county jails or state prisons.

(3) Treatment of addicts as provided for by *Section 11217.5 of the Health and Safety Code*.

(d) (1) For purposes of this section and Section 2241.5, "addict" means a person whose actions are characterized by craving in combination with one or more of the following: (A) Impaired control over drug use.
(B) Compulsive use.
(C) Continued use despite harm.

(2) Notwithstanding paragraph (1), a person whose drug-seeking behavior is primarily due to the inadequate control of pain is not an addict within the meaning of this section or Section 2241.5.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Within a context of prescribing to patients with a prior history or current status of addiction, clarifies for practitioners that there is an important distinction between addiction and pseudoaddiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to investigation just as other substandard practices might be.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written standards) to ensure competent review of pain management disciplinary cases.

Cal Bus & Prof Code § 2241.5

§ 2241.5. Administration of controlled substances to person experiencing pain, including "intractable pain"

(a) A physician and surgeon may prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain.

(b) No physician and surgeon shall be subject to disciplinary action for prescribing, dispensing, or administering dangerous drugs or prescription controlled substances in accordance with this section.

(c) This section shall not affect the power of the board to take any action described in Section 2227 against a physician and surgeon who does any of the following:

(1) Violates subdivision (b), (c), or (d) of Section 2234 regarding gross negligence, repeated negligent acts, or incompetence.

(2) Violates Section 2241 regarding treatment of an addict.

(3) Violates Section 2242 regarding performing an appropriate prior examination and the existence of a medical indication for prescribing, dispensing, or furnishing dangerous drugs.

(4) Violates Section 2242.1 regarding prescribing on the Internet.

(5) Fails to keep complete and accurate records of purchases and disposals of substances listed in the California Uniform Controlled Substances Act (Division 10 (commencing with *Section 11000) of the Health and Safety Code*) or controlled substances scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970 *(21 U.S.C. Sec. 801* et seq.), or pursuant to the federal Comprehensive Drug Abuse Prevention and Control Act of 1970. A physician and surgeon shall keep records of his or her purchases and disposals of these controlled substances or dangerous drugs, including the date of purchase, the date and records of the sale or disposal of the drugs by the physician and surgeon, the name and address of the person receiving the drugs, and the reason for the disposal or the dispensing of the drugs to the person, and shall otherwise comply with all state recordkeeping requirements for controlled substances.

(6) Writes false or fictitious prescriptions for controlled substances listed in the California Uniform Controlled Substances Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

(7) Prescribes, administers, or dispenses in violation of this chapter, or in violation of Chapter 4 (commencing with Section 11150) or Chapter 5 (commencing with *Section 11210) of Division 10 of the Health and Safety Code*.

(d) A physician and surgeon shall exercise reasonable care in determining whether a particular patient or condition, or the complexity of a patient's treatment, including, but not limited to, a current or recent pattern of drug abuse, requires consultation with, or referral to, a more qualified specialist.

(e) Nothing in this section shall prohibit the governing body of a hospital from taking disciplinary actions against a physician and surgeon pursuant to Sections 809.05, 809.4, and 809.5.

§ 2241.6. Development of standards for review of cases concerning management of a patient's pain

The Division of Medical Quality shall develop standards before June 1, 2002, to assure the competent review in cases concerning the management, including, but not limited to, the undertreatment, undermedication, and overmedication of a patient's pain. The division may consult with entities such as the American Pain Society, the American Academy of Pain Medicine, the California Society of Anesthesiologists, the California Chapter of the American College of Emergency Physicians, and any other medical entity specializing in pain control therapies to develop the standards utilizing, to the extent they are applicable, current authoritative clinical practice guidelines.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Cal Bus & Prof Code § 4301

§ 4301. Unprofessional conduct, procuring license by fraud or misrepresentation, or issuance of license by mistake

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

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(-) *CRITERION 16: Provisions that are ambiguous*

CATEGORY A: Arbitrary standards for legitimate prescribing

COMMENT: "Clearly excessive" implies there is a limit, but the limit is not specified.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pain Patient's Bill of Rights

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

California Health & Safety Code §124960

§ 124960. Legislative findings and declarations

The Legislature finds and declares all of the following:

(a) The state has a right and duty to control the illegal use of opiate drugs.

(b) Inadequate treatment of acute and chronic pain originating from cancer or noncancerous conditions is a significant health problem.

(c) For some patients, pain management is the single most important treatment a physician can provide.

(d) A patient suffering from severe chronic intractable pain should have access to proper treatment of his or her pain.

(e) Due to the complexity of their problems, many patients suffering from severe chronic intractable pain may require referral to a physician with expertise in the treatment of severe chronic intractable pain. In some cases, severe chronic intractable pain is best treated by a team of clinicians in order to address the associated physical, psychological, social, and vocational issues.

(f) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute and severe chronic intractable pain can be safe.

(g) Opiates can be an accepted treatment for patients in severe chronic intractable pain who have not obtained relief from any other means of treatment.

(h) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve his or her severe chronic intractable pain.

(i) A physician treating a patient who suffers from severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain as long as the prescribing is in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(j) A patient who suffers from severe chronic intractable pain has the option to choose opiate medication for the treatment of the severe chronic intractable pain as long as the prescribing is in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(k) The patient's physician may refuse to prescribe opiate medication for a patient who requests the treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Effect on Intractable Pain Treatment Act; Bill of Rights

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

California Health & Safety Code §124961

§ 124961. Effect on Intractable Pain Treatment Act; Bill of Rights

Nothing in this section shall be construed to alter any of the provisions set forth in the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code. This section shall be known as the Pain Patient's Bill of Rights.

(a) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her severe chronic intractable pain.

(b) A patient who suffers from severe chronic intractable pain has the option to choose opiate medications to relieve severe chronic intractable pain without first having to submit to an invasive medical procedure, which is defined as surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device, as long as the prescribing physician acts in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(c) The patient's physician may refuse to prescribe opiate medication for the patient who requests a treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates.

(d) A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain, as long as that prescribing is in conformance with the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(e) A patient may voluntarily request that his or her physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification.

(f) Nothing in this section shall do either of the following:

(1) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices or other provisions set forth in the Medical Practice Act, Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code, or the regulations adopted thereunder.

(2) Limit the applicability of any federal statute or federal regulation or any of the other statutes or regulations of this state that regulate dangerous drugs or controlled substances.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Sections (a) and (b) recognize the patient's right to choose or refuse different types of treatments.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: How does this qualify as a "Pain Patient's Bill of Rights" ? This language falls short of providing any rights to specific treatment and may establish a false expectation for adequate pain management.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: The phrase "severe chronic intractable pain" is used throughout this policy. The intended result of such elaborate and unconventional medical terminology is unclear, but appears to limit the patient population which should be given access to "proper treatment" of pain, including the use of opioids, and which is given the option to request or reject any treatments. What is the effect of this law on patients with pain that is not severe, chronic, and intractable? Is there a greater risk of discipline for a physician who would prescribe opioids to a patient with pain which was not severe, chronic, and intractable?

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY C:
Conflicting or inconsistent policies or provisions

COMMENT: This provision may be confusing, and even in conflict, when considered in conjunction with provision §124960(g) which states that patients qualify for opiate treatment after "other means of treatment;" in §124961(b), the patient does not have to "submit" to certain treatments.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

A STATEMENT BY THE MEDICAL BOARD

INTRODUCTION

The 1993 report of the Medical Board to the Governor signaled a new beginning in the history of medical regulation in California. An important part of this initiative is implementation of the recommendations made by the Board's Task Force on Appropriate Prescribing, chaired by Jacqueline Trestrail, M.D.

The Task Force was established to look into "malprescribing," one of the fastest growing categories of physician discipline. The Board continues to be concerned that controlled substances are subject to abuse by individuals who seek them for their mood altering and other psychological effects, rather than for legitimate medical purposes.

(+) *CRITERION 4:* *Encourages pain management*

The Board is also concerned about effective pain management and the appropriate medical use of controlled substances. During the Task Force's public meetings, the members heard testimony that some physicians avoid prescribing controlled substances, including the "triplicate" drugs, for patients with intractable pain for fear of discipline by the Board. The Task Force recommended that the Board take a pro-active approach to emphasize to all California physicians that it supports prescribing of opioid analgesics (narcotics) and other controlled substances when medically indicated for the treatment of pain, including intractable pain. After careful review of this matter, the Board concurs with the following statement.

(+) *CRITERION 3:* *Opioids are part of professional practice*

This statement is consistent with good medical practice, protection of public health and consumer interests, with international treaties, federal and California law, including the California Intractable Pain Treatment Act.

THE PAIN PROBLEM

The Board recognizes that pain, whether due to trauma, surgery, cancer and other diseases, is often undertreated. Minorities, women, children, the elderly and people with HIV/AIDS are at particular risk for under treatment of their pain. Unrelieved pain has a harsh and sometimes disastrous impact on the quality of life of people and their families.

While some progress is being made to improve pain and symptom management, the Board is concerned that a number of factors continue to interfere with effective pain management. These include the low priority of pain management in our health care system, incomplete integration of current knowledge into medical education and clinical practice, lack of knowledge among consumers about pain management, exaggerated fears of opioid side effects and addiction, and fear of legal consequences when controlled substances are used.

(+) *CRITERION 2:* *Pain management is part of medical practice*

PAIN MANAGEMENT SHOULD BE A HIGH PRIORITY IN CALIFORNIA

Principles of quality medical practice dictate that citizens of California who suffer from pain should be able to obtain the relief that is currently available. The Board believes that the appropriate application of current knowledge and treatments would greatly improve the quality of life for many California citizens, and could also reduce the morbidity and the costs that are associated with uncontrolled pain.

In addition to making this statement, the Board will take a number of steps to help make effective pain management a reality in California. The Board has provided information to all state physicians about new clinical practice guidelines for pain management that have been prepared by a panel of experts supported by the Agency for Health Care Policy and Research. The Board also co-sponsored and participated in the March 18, 1994 Pain Management and Appropriate Prescribing Summit in conjunction with the Department of Consumer Affairs on removing impediments to appropriate prescribing of controlled substances for effective pain management. Further, the Board will develop guidelines to help physicians avoid investigation if they appropriately prescribe controlled substances for pain management.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Prescribing Controlled Substances for Pain

THE APPROPRIATE ROLE OF OPIOID ANALGESICS
There are numerous drug and non-drug treatments that are used for the management of pain and other symptoms. The proper treatment of any patient's pain depends upon a careful diagnosis of the etiology of the pain, selection of appropriate and cost-effective treatments, and ongoing evaluation of the results of treatment. Opioid analgesics and other controlled substances are useful for the treatment of pain, and are considered the cornerstone of treatment of acute pain due to trauma, surgery and chronic pain due to progressive diseases such as cancer. Large doses may be necessary to control pain if it is severe. Extended therapy may be necessary if the pain is chronic.

The Board recognizes that opioid analgesics can also be useful in the treatment of patients with intractable non-malignant pain especially where efforts to remove the cause of pain or to treat it with other modalities have failed. The pain of such patients may have a number of different etiologies and may require several treatment modalities. In addition, the extent to which pain is associated with physical and psychosocial impairment varies greatly. Therefore, the selection of a patient for a trial of opioid therapy should be based upon a careful assessment of the pain as well as the disability experienced by the patient. Continuation of opioid therapy should be based on the physician's evaluation of the results of treatment, including the degree of pain relief, changes in physical and psychological functioning, and appropriate utilization of health care resources. Physicians should not hesitate to obtain consultation from legitimate practitioners who specialize in pain management.

The Board recommends that physicians pay particular attention to those patients who misuse their prescriptions, particularly when the patient or family have a history of substance abuse that could complicate pain management. The management of pain in such patients requires extra care and monitoring, as well as consultation with medical specialists whose area of expertise is substance abuse or pain management.

The Board believes that addiction should be placed into proper perspective. Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy and are not the same as addiction. Addiction is a behavioral syndrome characterized by psychological dependence and aberrant drug-related behaviors. Addicts compulsively use drugs for non-medical purposes despite harmful effects; a person who is addicted may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts or habitues merely because they are being treated with opioids.

PAIN MANAGEMENT, CONTROLLED SUBSTANCES AND THE LAW
The laws and regulations of the federal government and the State of California impose special requirements for the prescribing of controlled substances, including requirements as to the form of the prescription document, so as to prevent harm to the public health that is caused when prescription drugs are diverted to non-medical uses. For example, it is illegal to prescribe controlled substances solely to maintain narcotic addiction. However, federal and California law clearly recognize that it is a legitimate medical practice for physicians to prescribe controlled substances for the treatment of pain, including intractable pain.

The Medical Board will work with the Drug Enforcement Administration, the Bureau of Narcotic Enforcement, the Office of the Attorney General, the Board of Pharmacy and its own investigators in an attempt to develop policy and guidelines based on the physician's diagnosis and treatment program rather than amounts of drugs prescribed.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Concerns about regulatory scrutiny should not make physicians who follow appropriate guidelines reluctant to prescribe or administer controlled substances, including Schedule II drugs, for patients with a legitimate medical need for them. A physician is not subject to Board action when prescribing in the regular course of his or her profession to one under the physician's treatment for a pathology or condition and where the prescription is issued after a good faith examination and where there is medical indication for the drug. Good faith prescribing requires an equally good faith history, physical examination and documentation.

The Medical Board may identify a pattern of controlled substance use that merits further examination. A private, courteous and professional inquiry can usually determine whether the physician is in good faith appropriately prescribing for patients, or whether an investigation is necessary. The Board will judge the validity of prescribing based on the physician's diagnosis and treatment of the patient and whether the drugs prescribed by the physician are appropriate for that condition, and will not act on the basis of predetermined numerical limits on dosages or length of drug therapy.

The Board hopes to replace practitioners' perception of inappropriate regulatory scrutiny with recognition of the Board's commitment to enhance the quality of life of patients by improving pain management while, at the same time, preventing the diversion and abuse of controlled substances.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Text of "Guideline for Prescribing Controlled Substances for Intractable Pain"
Adopted Unanimously by the Board in 1994 and Recently Revised

"No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain." -Business and Professions Code §2241.5(c)

PREAMBLE

In 1994, the Medical Board of California formally adopted a policy statement titled, "Prescribing Controlled Substances for Pain." The statement outlined the Board's proactive approach to improving appropriate prescribing for effective pain management in California, while preventing drug diversion and abuse. The policy statement was the product of a year of research, hearings and discussions. California physicians and surgeons are encouraged to consult the policy statement and these guidelines, which can be found at www.medbd.ca.gov or obtained from the Medical Board of California.

In May 2002, as a result of AB 487, a task force was established to review the 1994 Guidelines and to assist the Division of Medical Quality to "develop standards to assure the competent review in cases concerning the management, including, but not limited to, the under treatment, under medication, and over medication of a patient's pain." The task force expanded the scope of the Guidelines, from intractable pain patients to all patients with pain.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(CONTINUED)

Inappropriate prescribing of controlled substances, including opioids, can lead to drug abuse or diversion and can also lead to ineffective management of pain, unnecessary suffering of patients, and increased health costs. The Medical Board recognizes that some physicians do not treat pain appropriately due to a lack of knowledge or concern about pain, and others may fail to treat pain properly due to fear of discipline by the Medical Board. These Guidelines are intended to improve effective pain management in California, by avoiding under treatment, over treatment, or other inappropriate treatment of a patient's pain and by clarifying the principles of professional practice that are endorsed by the Medical Board so that physicians have a higher level of comfort in using controlled substances, including opioids, in the treatment of pain. These Guidelines are intended to promote improved pain management for all forms of pain and for all patients in pain.

(+) *CRITERION 4:*
Encourages pain management

A HIGH PRIORITY

(+) *CRITERION 2:*
Pain management is part of medical practice

The Board strongly urges physicians and surgeons to view effective pain management as a high priority in all patients, including children, the elderly, and patients who are terminally ill. Pain should be assessed and treated promptly, effectively and for as long as pain persists. The medical management of pain should be based on up-to-date knowledge about pain, pain assessment and pain treatment. Pain treatment may involve the use of several medications and non-pharmacological treatment modalities, often in combination. For some types of pain, the use of medications is emphasized and should be pursued vigorously; for other types, the use of medications is better de-emphasized in favor of other therapeutic modalities. Physicians and surgeons should have sufficient knowledge or utilize consultations to make such judgments for their patients.

(+) *CRITERION 3:*
Opioids are part of professional practice

Medications, in particular opioid analgesics, are considered the cornerstone of treatment for pain associated with trauma, surgery, medical procedures, or cancer. A number of medical organizations have developed guidelines for acute and chronic pain management. Links to these references may be found on the Medical Board of California's Web site at ww.medbd.ca.gov.

The prescribing of opioid analgesics for patients with pain, may also be beneficial, especially when efforts to alleviate the pain with other modalities have been unsuccessful.

Intractable pain is defined by law in California as: "a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain." (Section 2241.5(b) of the California Business and Professions Code)

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Physicians and surgeons who prescribe opioids either for acute or persistent pain should not fear disciplinary or other action from California law enforcement or regulatory agencies for the mere fact of having prescribed opioids. The appropriate use of opioids in the treatment of intractable pain has long been recognized in California's Intractable Pain Treatment Act, which provides that "No physician and surgeon shall be subject to disciplinary action by the Medical Board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain." (Section 2241.5(c) of the California Business and Professions Code) The Medical Board expects physicians and surgeons to follow the standard of care in managing pain patients.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(CONTINUED)

GUIDELINES

• History/Physical Examination A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; an assessment of underlying or coexisting diseases or conditions; and documentation of the presence of a recognized medical indication for the use of a controlled substance.

Annotation One: The prescribing of controlled substances for pain may require referral to one or more consulting physicians.

Annotation Two: The complexity of the history and physical examination may vary based on the practice location. In the emergency department, the operating room, at night or on the weekends, the physician and surgeon may not always be able to verify the patient's history and past medical treatment. In continuing care situations for chronic pain management, the physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests and physical exam.

• Treatment Plan, Objectives The treatment plan should state objectives by which the treatment plan can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician and surgeon should tailor pharmacological therapy to the individual medical needs of each patient. Multiple treatment modalities and/or a rehabilitation program may be necessary if the pain is complex or is associated with physical and psychosocial impairment.

Annotation One: Physicians and surgeons may use control of pain, increase in function, and improved quality of life as criteria to evaluate the treatment plan.

Annotation Two: When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

• Informed Consent The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian.

Annotation: A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient's use of medications for relief from pain.

• Periodic Review The physician and surgeon should periodically review the course of pain treatment of the patient and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient's progress is unsatisfactory, the physician and surgeon should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Annotation One: Patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care.

Annotation Two: Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

• **Consultation** The physician and surgeon should consider referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Complex pain problems may require consultation with a pain medicine specialist.

In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists, and may entail the use of agreements between the provider and the patient that specify the rules for medication use and consequences for misuse.

Annotation One: Coordination of care in prescribing chronic analgesics is of paramount importance.

Annotation Two: In situations where there is dual diagnosis of opioid dependence and intractable pain, both of which are being treated with controlled substances, protections apply to physicians and surgeons who prescribe controlled substances for intractable pain provided the physician complies with the requirements of the general standard of care and California Business and Professions Code section 2241.5.

• **Records** The physician and surgeon should keep accurate and complete records according to items above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, rationale for changes in the treatment plan or medications, agreements with the patient, and periodic reviews of the treatment plan.

Annotation One: Documentation of the periodic reviews should be done at least annually or more frequently as warranted.

Annotation Two: Pain levels, levels of function, and quality of life should be documented. Medical documentation should include both subjective complaints of patient and caregiver, and objective findings by the physician.

• **Compliance with Controlled Substances Laws and Regulations** To prescribe controlled substances, the physician and surgeon must be appropriately licensed in California, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians and surgeons are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the Medical Board's Guidebook to Laws Governing the Practice of Medicine by Physicians and Surgeons for specific rules governing issuance of controlled substances prescriptions.

(+) *CRITERION 6:* *Prescription amount alone does not determine legitimacy*

Annotation One: There is not a minimum or maximum number of medications which can be prescribed to the patient under either federal or California law.

Annotation Two: Physicians and surgeons who supervise Physician Assistants (PA's) or Nurse Practitioners (NP's) should carefully review the respective supervision requirements.

Additional information on PA supervision requirements is available at www.physicianassistant.ca.gov.

PA's are able to obtain their own DEA number to use when writing prescriptions for drug orders for controlled substances. Current law permits physician assistants to write and sign prescription drug orders when authorized to do so by their supervising physician for Schedule II-IV. Further, a PA may only administer, provide or transmit a drug order for

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

To ensure that a PA's actions involving the prescribing, administration, or dispensing of drugs is in strict accordance with the directions of the physician, every time a PA administers or dispenses a drug or transmits a drug order, the physician supervisor must sign and date the patient's medical record or drug chart within seven days. (Section 1399.545(f) of the California Code of Regulations)

NP's are allowed to furnish Schedule III-V controlled substances under written protocols.

POSTSCRIPT

While it is lawful under both federal and California law to prescribe controlled substances for the treatment of pain, there are limitations on the prescribing of controlled substances to or for patients for the treatment of chemical dependency (see Sections 11215-11222 of the California Health and Safety Code). The California Intractable Pain Treatment Act (CIPTA) does not apply to those persons being treated by the physician and surgeon only for chemical dependency because of use of drugs or controlled substances (Section 2241.5(d)). The CIPTA does not authorize a physician and surgeon to prescribe, dispense, or administer controlled substances to a person the practitioner knows to be using the prescribed drugs or controlled substances for non-therapeutic purposes (Section 2241.5(e)). At the same time, California law permits the prescribing, furnishing, or administering of controlled substances to or for a patient who is suffering from disease, ailments, injury, or infirmities attendant on old age, other than addiction (Section 11210 of the California Health and Safety Code) and the CIPTA does apply to "a practitioner who is prescribing controlled substances for intractable pain, and as long as that practitioner is not also treating the patient for chemical dependency."

The Medical Board emphasizes the above issues, both to ensure physicians and surgeons know that a patient in pain who is also chemically dependent should not be deprived of appropriate pain relief, and to recognize the special issues and difficulties associated with patients who suffer both from drug addiction and pain. The Medical Board expects that the acute pain from trauma or surgery will be addressed regardless of the patient's current or prior history of substance abuse. This postscript should not be interpreted as a deterrent for appropriate treatment of pain.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Pharmacy Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 4: Encourages pain management*

DISPENSING CONTROLLED SUBSTANCES FOR PAIN

INTRODUCTION
Healthcare leaders and patient advocates from throughout California met at the Summit on Effective Pain Management: Removing Impediments to Appropriate Prescribing in Los Angeles in 1994 to discuss the effective management of pain. Summit participants concurred that effective pain management, including the use of controlled substance medications, is essential to the health and welfare of Californians experiencing pain. It was also concluded that inappropriate or undertreatment of pain is serious and wide spread.

In response to these findings, the California State Board of Pharmacy is taking a leadership role in promoting the effective management of pain for the state's citizens. The Board's objectives include educating pharmacists on advances in appropriate pain management and taking active roles in providing this therapy. The Board is working to computerize the triplicate prescription program; is encouraging the timely availability of opioids in different healthcare settings such as hospitals, patient's homes and pharmacies; and is encouraging better knowledge and attitudes of patients, the public and other licensed healthcare professionals in the use of pain medications-all with the goal of positively influencing the care of patients in pain.

The Board of Pharmacy must ensure that laws, regulations, policies, and practices promote the availability and use of controlled substance drugs to patients for legitimate pain management. The Board encourages programs to help educate patients, the public, and licensed healthcare professionals about the effective use of medications in the treatment of various types of pain. The Board also recognizes that, with proper assessment, therapeutic planning, and follow up, medications should be available and used when needed.

The pharmacist's role (as educator and manager) in providing drug therapy for patients in pain is extensive. If pharmacists are to provide complete pain management services, they must fulfill their responsibilities to:

1. Facilitate the dispensing of legitimate prescriptions;

2. Understand and learn about the effective uses of all pain medications, especially opioids and other controlled substances, in the management of pain;

3. Carefully explain dosage regimens, and discuss potential side effects of pain medications;

4. Monitor and assess the patient for effective pain therapy outcomes, evaluate compliance, assess for tolerance to opioids, and ensure subsequent dosage adjustments as needed;

5. Obtain, retain, and update appropriate information documenting the course of, and need for, on-going opioid therapy;

6. Encourage patients to talk with their pharmacist about their medications, the benefits and problems;

7. Discuss and allay patients' possible fear of addiction with the use of narcotics where this is a factor;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Pharmacy Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

8. Watch for patients who misuse their prescriptions and be especially aware of a patient or family history of substance abuse that might complicate pain management and act accordingly;

9. Assess the patient for adverse drug reactions from the pain therapy regimen and take action to minimize or eliminate them;

10. Be aware of and recommend non-medication treatments for pain or refer patients for such when appropriate;

11. Evaluate OTC, prescription drugs, and alcohol taken with pain medications for potential drug interactions;

12. Recognize that patients and caregivers are important sources of information in assessing the patient's pain therapy;

13. Act as a liaison between patients and other healthcare providers, ensuring that there is open communication and understanding about the drugs patients are taking to reduce pain; and

14. Optimize pain management so patients can reach their highest level of functioning and quality of life.

ROLE OF OPIOIDS IN PAIN MANAGEMENT

Many patients with cancer or chronic medical conditions experience moderate to severe pain that is often inappropriately treated or undermedicated. Pain can have a negative effect on the patient's health and quality of life resulting in needless suffering, emotional distress, loss of productivity and possibly slower recovery from illness, injury, and disease.

Although there have been significant advances in knowledge about pain and the use of opioids and other medications in pain management, many licensed healthcare professionals prescribe, dispense, or administer these medications suboptimally. There is a misconception by patients, the public, and some licensed healthcare providers that opioids are "bad" drugs because opioids are often associated with drug abuse, addiction, and criminal activity. Studies have shown that opioids used appropriately for pain management have an extremely low potential for abuse.

(+) *CRITERION 6:* *Prescription amount alone does not determine legitimacy*

The Board understands that the ongoing use of opioids for cancer, post-surgical, and chronic pain is not what causes addiction or a patient's desire for higher doses of pain medication. Patients suffering from extreme pain or progression of disease may require increased doses of medication; the appropriate dose is that which is required to adequately treat the pain, even if the dose is higher than usually expected. In addition, with long-term treatment of pain with opioids, patients may develop a tolerance to the drug or a dependence on the drug. These occurrences are considered "normal" and "to be expected" - they should not be confused by the licensed healthcare professional with drug addiction or be mislabeled as "drug seeking."

(+) *CRITERION 7:* *Physical dependence or analgesic tolerance are not confused with "addiction"*

The Board understands that an important part of effective pain management is ensuring that patients do not have difficulty obtaining adequate medication for pain relief. The Board recognizes that it is the professional responsibility of the pharmacist to recommend that patients in pain receive appropriate, timely, and adequate drug therapy to reduce their pain.

(+) *CRITERION 3:* *Opioids are part of professional practice*

CONCLUSION

Recognition of the utility of opioids and other controlled substance drugs for the treatment of pain resulting from a variety of conditions is well established. The need for regulators and practitioners to understand this use, and to adopt laws, policies, and practices is self-evident if patients are to receive relief from pain which is now medically possible. In addition, pharmacists must understand their role in the on-going monitoring and assessment of patients' pain management. Working cooperatively, the Board of Pharmacy and the profession can ensure that opioids and other controlled substance drugs are used appropriately and effectively.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Reports of Injuries

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (protocols for interagency investigations) to ensure competent review of pain management cases.

Cal Pen Code § 11161.5

§ 11161.5. Legislative intent regarding development of protocols for interagency investigations of a physician's prescription of medication to patients

(a) It is the intent of the Legislature that on or before January 1, 2006, the California District Attorneys Association, in conjunction with interested parties, including, but not limited to, the Department of Justice, the California Narcotic Officers' Association, the California Police Chiefs' Association, the California State Sheriffs' Association, the California Medical Association, the American Pain Society, the American Academy of Pain Medicine, the California Society of Anesthesiologists, the California Chapter of the American College of Emergency Physicians, the California Medical Board, the California Orthopedic Association, and other medical and patient advocacy entities specializing in pain control therapies, shall develop protocols for the development and implementation of interagency investigations in connection with a physician's prescription of medication to patients. The protocols are intended to assure the competent review of, and that relevant investigation procedures are followed for, the suspected undertreatment, undermedication, overtreatment, and overmedication of pain cases. Consideration shall be made for the special circumstances of urban and rural communities. The investigation protocol shall be designed to facilitate communication between the medical and law enforcement communities and the timely return of medical records pertaining to the identity, diagnosis, prognosis, or treatment of any patient that are seized by law enforcement from a physician who is suspected of engaging in or having engaged in criminal activity related to the documents.

(b) The costs incurred by the California District Attorneys Association in implementing this section shall be solicited and funded from nongovernmental entities.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to investigation just as other substandard practices might be.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Health Facility Licensing

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Cal Health & Saf Code § 1254.7

§ 1254.7. Pain assessment

(a) It is the intent of the Legislature that pain be assessed and treated promptly, effectively, and for as long as pain persists.

(b) Every health facility licensed pursuant to this chapter shall, as a condition of licensure, include pain as an item to be assessed at the same time as vital signs are taken. The health facility shall ensure that pain assessment is performed in a consistent manner that is appropriate to the patient. The pain assessment shall be noted in the patient's chart in a manner consistent with other vital signs.

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Cal Health & Saf Code § 1262.6

§ 1262.6. Patient's rights information requirements provided by hospital

(a) Each hospital shall provide each patient, upon admission or as soon thereafter as reasonably practical, written information regarding the patient's right to the following:

(1) To be informed of continuing health care requirements following discharge from the hospital.

(2) To be informed that, if the patient so authorizes, that a friend or family member may be provided information about the patient's continuing health care requirements following discharge from the hospital.

(3) Participate actively in decisions regarding medical care. To the extent permitted by law, participation shall include the right to refuse treatment.

(4) Appropriate pain assessment and treatment consistent with Sections 124960 and 124961.

(b) A hospital may include the information required by this section with other notices to the patient regarding patient rights. If a hospital chooses to include this information along with existing notices to the patient regarding patient rights, this information shall be provided when the hospital exhausts its existing inventory of written materials and prints new written materials.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for health facilities to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospice Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

28 CCR 1300.68.2

§ 1300.68.2. Hospice Services

(a) For purposes of this section, the following definitions shall apply:

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(2) "Hospice service" or "hospice program" means a specialized form of interdisciplinary health care that is designed to provide palliative care, alleviate the physical, emotional, social and spiritual discomforts of an enrollee who is experiencing the last phases of life due to the existence of a terminal disease, to provide supportive care to the primary care giver and the family of the hospice patient, and which meets all of the following criteria;

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(C) Requires the interdisciplinary team to develop an overall plan of care and to provide coordinated care which emphasizes supportive services, including, but not limited to, home care, pain control, and short-term inpatient services. Short-term inpatient services are intended to ensure both continuity of care and appropriateness of services for those enrollees who cannot be managed at home because of acute complications or the temporary absence of a capable primary caregiver.

(D) Provides for the palliative medical treatment of pain and other symptoms associated with a terminal disease, but does not provide for efforts to cure the disease.

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(7) "Medical direction" means those services provided by a licensed physician and surgeon who is charged with the responsibility of acting as a consultant to the interdisciplinary team, a consultant to the enrollee's attending physician and surgeon, as requested, with regard to pain and symptom management, and liaison with physicians and surgeons in the community. For purposes of this section, the person providing these services shall be referred to as the "medical director."

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes mechanisms for hospices to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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COLORADO

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 18. Criminal Code; Article 18. Uniform Controlled Substances Act of 1992

- MEDICAL PRACTICE ACT
  Title 12. Professions and Occupations; Health Care; Article 36. Medical Practice

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Title 12. Professions and Occupations; Health Care; Article 36. Medical Practice; Part 1. General Provisions

- PHARMACY PRACTICE ACT
  Title 12. Professions and Occupations; General; Article 22. Pharmaceuticals and Pharmacists

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  No policy found

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Department of Regulatory Agencies; Board of Medical Examiners

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Department of Regulatory Agencies; State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Colorado State Board of Medical Examiners. *Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: November 18, 2004.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- OFFENSES AGAINST THE PERSON
  Title 18. Criminal Code; Article 3. Offenses Against the Person

- STANDARDS FOR HOSPITALS AND HEALTH FACILITIES
  Department of Public Health and Environment; Health Facilities and Emergency Medical Services Division

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Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act		●	●					
Medical Practice Act		●						
Intractable Pain Treatment Act					●			
Pharmacy Practice Act			●					
REGULATIONS								
Controlled Substances[2]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Offenses Against the Person		●						●
Standards for Hospitals and Health Facilities								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Intractable Pain Treatment Act		●		●				●
Pharmacy Practice Act			●					
REGULATIONS								
Controlled Substances[2]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Offenses Against the Person[1]								
Standards for Hospitals and Health Facilities[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

COLORADO

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

C.R.S. 18-18-102

18-18-102. Definitions

As used in this article:

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(29) "Practitioner" means a physician, podiatrist, dentist, optometrist, veterinarian, researcher, pharmacist, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by this state, to distribute, dispense, conduct research with respect to, administer, or to use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

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(+) *CRITERION 3:*
Opioids are part of professional practice

C.R.S. 18-18-308

18-18-308. Prescriptions

(1) As used in this section, "medical treatment" includes dispensing or administering a narcotic drug for pain, including intractable pain.

(2) Except as provided in section 18-18-414, a person may dispense a controlled substance only as provided in this section.

(3) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a substance included in schedule II may not be dispensed without the written prescription of a practitioner.

(4) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a substance included in schedule III, IV, or V may not be dispensed without a written or oral prescription order of a practitioner. The prescription order must not be filled or refilled more than six months after the date thereof or be refilled more than five times.

(5) A practitioner may dispense or deliver a controlled substance to or for an individual or animal only for medical treatment or authorized research in the ordinary course of that practitioner's profession.

(6) No civil or criminal liability or administrative sanction may be imposed on a pharmacist for action taken in reliance on a reasonable belief that an order purporting to be a prescription was issued by a practitioner in the usual course of professional treatment or in authorized research.

(+) *CRITERION 2:*
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

COLORADO

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

C.R.S. 12-36-106

12-36-106. Practice of medicine defined - exemptions from licensing requirements - repeal

(1) For the purpose of this article, "practice of medicine" means:

(a) Holding out one's self to the public within this state as being able to diagnose, treat, prescribe for, palliate, or prevent any human disease, ailment, pain, injury, deformity, or physical or mental condition, whether by the use of drugs, surgery, manipulation, electricity, telemedicine, the interpretation of tests, including primary diagnosis of pathology specimens, images, or photographs, or any physical, mechanical, or other means whatsoever;

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(+) *CRITERION 2:*
Pain management is part of medical practice

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

C.R.S. 12-36-117

12-36-117. Unprofessional conduct

(1) "Unprofessional conduct" as used in this article means:

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(hh) Advertising in a manner that is misleading, deceptive, or false;

(ii) Entering into or continuing a collaborative agreement pursuant to sections 12-38-111.6 (4) (d) (IV) and 12-36-106.3 that fails to meet generally acceptable standards of medical practice.

(1.5) (a) A licensee shall not be subject to disciplinary action by the board solely for prescribing controlled substances for the relief of intractable pain.

(b) For the purposes of this subsection (1.5), "intractable pain" means a pain state in which the cause of the pain cannot be removed and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and one or more physicians specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(-) *CRITERION 10:*
Implies opioids are not part of professional

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY B:
Mandated consultation

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

COLORADO

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

C.R.S. 12-22-303

12-22-303. Definitions

As used in this part 3, unless the context otherwise requires:

(1) "Addict" means a person who has a physical or psychological dependence on a controlled substance, which dependence develops following the use of the controlled substance on a periodic or continuing basis and is demonstrated by appropriate observation and tests by a person licensed to practice medicine pursuant to article 36 of this title.

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12-22-702. Definitions

As used in this part 7, unless the context otherwise requires:

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(6) "Practitioner" shall have the same meaning as in *section 18-18-102 (29), C.R.S.* By reference: "Practitioner" means a physician, podiatrist, dentist, optometrist, veterinarian, researcher, pharmacist, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by this state, to distribute, dispense, conduct research with respect to, administer, or to use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

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(+) *CRITERION 3:* *Opioids are part of professional practice*

(-) *CRITERION 11:* *Physical dependence or analgesic tolerance confused with "addiction"*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

COLORADO

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

COLORADO STATE BOARD OF MEDICAL EXAMINERS
POLICY FOR THE USE OF CONTROLLED SUBSTANCES
FOR THE TREATMENT OF PAIN

Section I: Preamble

The Colorado State Board of Medical Examiners ("Board") recognizes that principles of quality medical practice dictate that the people of the State of Colorado have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.
Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations just as diligently as it would allegations of other misconduct relating to prescribing practices, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Board is obligated under the laws of the State of Colorado to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

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(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

COLORADO

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Physicians should not fear disciplinary action from the Board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. If such prescribing meets these criteria, the Board will support physicians whose use of controlled substances has been questioned by another regulatory or enforcement agency. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for not adhering strictly to this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

1. Evaluation of the Patient
A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan
The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment
The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

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(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. Periodic Review
The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

5. Consultation
The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records
The physician should keep accurate and complete records to include

- the medical history and physical examination;
- diagnostic, therapeutic and laboratory results;
- evaluations and consultations;
- treatment objectives;
- discussion of risks and benefits;
- informed consent;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- periodic reviews.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations
To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction
Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain
Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence
Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction
The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

COLORADO

STATUTES

Offenses Against the Person

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

C.R.S. 18-3-104

18-3-104. Manslaughter

(1) A person commits the crime of manslaughter if:

(a) Such person recklessly causes the death of another person; or

(b) Such person intentionally causes or aids another person to commit suicide.

(c) (Deleted by amendment, L. 96, p. 1844, § 13, effective July 1, 1996.)

(2) Manslaughter is a class 4 felony.

(3) This section shall not apply to a person, including a proxy decision-maker as such person is described in *section 15-18.5-103, C.R.S.*, who complies with any advance medical directive in accordance with the provisions of title 15, C.R.S., including a medical durable power of attorney, a living will, or a cardiopulmonary resuscitation (CPR) directive.

(4) (a) This section shall not apply to a medical caregiver with prescriptive authority or authority to administer medication who prescribes or administers medication for palliative care to a terminally ill patient with the consent of the terminally ill patient or his or her agent.

(b) For purposes of this subsection (4):

(I) "Agent" means a person appointed to represent the interests of the terminally ill patient by a medical power of attorney, power of attorney, health care proxy, or any other similar statutory or regular procedure used for designation of such person.

(II) "Medical caregiver" means a physician, registered nurse, nurse practitioner, or physician assistant licensed by this state.

(III) "Palliative care" means medical care and treatment provided by a licensed medical caregiver to a patient with an advanced chronic or terminal illness whose condition may not be responsive to curative treatment and who is, therefore, receiving treatment that relieves pain and suffering and supports the best possible quality of his or her life.

(c) Paragraph (a) of this subsection (4) shall not be interpreted to permit a medical caregiver to assist in the suicide of the patient.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for practitioners that there is an important distinction between manslaughter and prescribing controlled substances for palliative care; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment and the professionals who provide it.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

COLORADO

REGULATIONS

Standards for Hospitals and Health Facilities

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written policies) for hospices to ensure that pain management is an essential part of patient care.

6 CCR 1011-1

6 CCR 1011-1. STANDARDS FOR HOSPITALS AND HEALTH FACILITIES

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6. POLICIES AND PROCEDURES

6.1 Under the supervision and direction of the Governing Body, the hospice shall develop and implement written policies to coordinate a program for home and inpatient hospice care services.
6.1.1 These policies and procedures shall be reviewed and approved by the Governing Body annually.
6.1.2 The policies and procedures shall include but not be limited to:
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a) pain and other symptoms.
b) physical components of care.
c) financial needs.
d) contractual services.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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CONNECTICUT

Citations for Policies Evaluated

STATUTES

- UNIFORM CONTROLLED SUBSTANCES ACT
  Title 21a. Consumer Protection; Chapter 420b. Dependency-Producing Drugs

- MEDICAL PRACTICE ACT
  Title 20. Professional and Occupational Licensing; Certification, Title Protection and Registration; Examining Boards; Chapter 370. Medicine and Surgery

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 20. Professional and Occupational Licensing; Certification, Title Protection and Registration; Examining Boards; Chapter 400j. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 21a. Consumer Protection; Department of Consumer Protection; Designation of Controlled Drugs

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 20. Professional Licenses; Connecticut Medical Examining Board

- Pharmacy Board Regulations (*No provisions found*)
  Title 20. Professional Licenses; Commission of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Connecticut Medical Examining Board. *Statement of the Connecticut Medical Examining Board on the Use of Controlled Substances for the Treatment of Pain*. Adopted: June 21, 2005.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HEALTH CARE INSTITUTIONS
  Title 19a. Health and Well-Being; Chapter 368v. Health Care Institutions.

- LICENSURE OF HOME HEALTH CARE AGENCIES
  Title 19. Health and Safety; Department of Public Health and Addiction Services; The Public Health Code of the State of Connecticut; Chapter IV. Hospitals, Child Day Care Centers, Other Institutions and Children's Licensure of Home Health Care Agencies.

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					●
Medical Practice Act			●					
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●		●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Health Care Institutions								●
Licensure of Home Health Care Agencies								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act						●		
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances				●				
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guidelines[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Health Care Institutions[1]								
Licensure of Home Health Care Agencies[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

CONNECTICUT

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

Conn. Gen. Stat. § 21a-240

§ 21a-240. (Formerly Sec. 19-443). Definitions.

The following words and phrases, as used in this chapter, shall have the following meanings, unless the context otherwise requires:

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(43) "Practitioner" means: (A) A physician, dentist, veterinarian, podiatrist, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state; (B) a pharmacy, hospital or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state;

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Conn. Gen. Stat. § 21a-251

§ 21a-251. (Formerly Sec. 19-459). Dispensing of controlled substances by hospitals, infirmaries or clinics.

(a) No controlled substances shall be dispensed or administered by hospitals, infirmaries or clinics except upon written order signed or initialed by the prescribing practitioner or upon an oral order of a prescribing practitioner which shall be confirmed by a written order which shall be signed or initialed by such prescribing practitioner within twenty-four hours after the giving of such oral order for schedule II controlled substances and within seventy-two hours after the giving of such oral order for other controlled substances.

(b) Original and continuing orders for schedule II controlled substances shall be limited to a period not exceeding seven days from the time the order is entered, but may be extended for additional periods of seven days each by the signing or initialing of the order by a prescribing practitioner.

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(-) *CRITERION 14:*
Undue prescription requirements

COMMENT: Stop-orders for controlled substances typically are found in institutional policy, but this establishes a specific requirement under the Connecticut Controlled Substances Act, which is largely a criminal statute. Is such a policy appropriate in a state CSA?

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

CONNECTICUT

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Conn. Gen. Stat. § 21a-254

§ 21a-254. (Formerly Sec. 19-461). Designation of restricted drugs or substances by regulations. Records required by chapter. Establishment of electronic prescription drug monitoring program. Pharmacy and outpatient pharmacy controlled substance prescription reporting. Vendor collection of information. Confidentiality. Disclosure of information. Regulations.

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(j) (1) The commissioner shall, within available appropriations, establish an electronic prescription drug monitoring program to collect, by electronic means, prescription information for schedules II, III, IV and V controlled substances, as defined in subdivision (9) of *section 21a-240*, that are dispensed by pharmacies and outpatient pharmacies in hospitals or institutions. The program shall be designed to provide information regarding the prescription of controlled substances in order to prevent the improper or illegal use of the controlled substances and shall not infringe on the legitimate prescribing of a controlled substance by a prescribing practitioner acting in good faith and in the course of professional practice.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

Conn. Gen. Stat. § 21a-254a

§ 21a-254a. Appointment of prescription drug monitoring working group. Membership.

The Commissioner of Consumer Protection shall appoint a prescription drug monitoring working group for the purpose of advising the commissioner on the implementation of the electronic prescription drug monitoring program established pursuant to *section 21a-254*, including the adoption of regulations by the commissioner. Such advice shall include, but not be limited to, recommendations on how to effectively use the data collected pursuant to such program to detect fraud while protecting the legitimate use of controlled substances. The working group shall include, but not be limited to: (1) A physician, licensed pursuant to chapter 370, specializing in internal medicine; (2) a board certified oncologist; (3) a person licensed to perform advanced level nursing practice activities pursuant to subsection (b) of *section 20-87a*; (4) a representative from an acute care hospital licensed pursuant to chapter 368v; (5) a state police officer appointed in accordance with *section 29-4*; (6) a municipal police chief; (7) a representative from the Division of Criminal Justice; (8) a representative from a hospice licensed by the Department of Public Health or certified pursuant to *42 USC 1395x;* (9) a pain management specialist, as defined in *section 38a-492i;* (10) a pharmacist licensed pursuant to *section 20-590*, *20-591* or *20-592*; and (11) a representative from the Department of Mental Health and Addiction Services.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (review by working group member who is a pain management specialist) to appropriately interpret prescription monitoring program information.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

CONNECTICUT

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

Conn. Gen. Stat. § 20-14c

§ 20-14c. Dispensing and labeling of drugs. Definitions.

As used in this section and *sections 20-14d* to *20-14g*, inclusive, and *section 20-12d*:

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(3) "Prescribing practitioner" means a physician, dentist, podiatrist, optometrist, physician assistant, advanced practice registered nurse, nurse-midwife or veterinarian licensed by the state of Connecticut and authorized to prescribe medication within the scope of such person's practice.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

CONNECTICUT

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

Regs., Conn. State Agencies § 21a-326-1

Sec. 21a-326-1. Definitions

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(c) "Course of Professional Practice" means the limitation of prescribing, dispensing, or administering of controlled substances for professional treatment authorized pursuant to regulations and/or statutes of the appropriate state licensing authority under which situations there must be a bona fide practitioner-patient relationship. The prescribing or dispensing of controlled substances for patients, friends, relatives, associates, and/or employees wherein a bona fide practitioner-patient relationship does not exist or wherein the practitioner has not medically evaluated the need for controlled substances shall not be considered to be in the "course of professional practice."

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(e) "Therapeutic or Other Proper Medical or Scientific Purposes" means the following: (1) The prescribing, dispensing, or administering of a controlled substance for treatment of a specific disease or medical condition, recognized by medical consensus and/or stated in the literature of the manufacturers of the controlled substances as being the purposes for which the controlled substance is intended.

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(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY D:
Undue prescription limitations

COMMENT: Under Federal law, physicians are not restricted to FDA approved indications listed in the manufacturer's literature. Because prescribing for other than (e) is considered unprofessional conduct, it appears that "off label" prescribing of controlled substances would be unprofessional conduct. Also, what constitutes a "medical consensus" and who determines this?

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

CONNECTICUT

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Statement of the Connecticut Medical Examining Board on the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Connecticut Medical Examining Board (Board) recognizes that principles of quality medical practice dictate that the people of the State of Connecticut have access to appropriate and effective pain relief. The purpose of this statement is to express the Board's support for the development and implementation of practices to assure the appropriate application of up-to-date knowledge and treatment modalities which can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this Statement, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. Therefore, the Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain in conjunction with terminal illness. All physicians and health care professionals should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory and regulatory requirements for prescribing controlled substances. Accordingly this Statement has been developed to encourage physicians to consider the importance of pain control, particularly as related to the use of controlled substances and to encourage comprehensive pain management.

The Board recognizes that applicable standards of care permit the use of controlled substances including opioid analgesics in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board also believes that physicians should be able to prescribe, dispense or administer controlled substances, including opioid analgesics, when done for a legitimate medical purpose and in accord with applicable standards of care and applicable law. The Board recognizes that the aim of current practice guidelines is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. Current practice guidelines accept that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not pathognomonic of addiction.

The Board acknowledges the medical community's view that the goals of effective pain management include (i) pain is to be assessed and treated promptly; (ii) the amount of medication and frequency of dosing adjusted according to the intensity, duration of the pain, and treatment outcomes; (iii) consideration of current clinical knowledge and scientific research; and (iv) the use of pharmacologic and non-pharmacologic modalities.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) ***CRITERION 6:*** ***Prescription amount alone does not determine legitimacy***

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The Board is obligated under the laws of the State of Connecticut to protect the public health and safety. Connecticut law reflects the public policy that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, current practice guidelines also note that effective pain management incorporates safeguards into the practice to minimize the potential for the abuse and diversion of controlled substances such as periodic reviews and written agreements outlining patient responsibility. However, physicians may face serious questions as to the legitimate medical purpose of a prescription where no physician-patient relationship exists or the prescription is not based on a diagnosis and clear documentation of pain.

As in all proceedings, matters involving issues of pain management will be reviewed and decided on a case-by-case basis. The Board may consider clinical practice guidelines, expert opinions, witness testimony, medical records and other relevant evidence. In accord with its case-by-case approach to such cases, the Board may not judge the validity of treatment solely on the quantity and duration of medication administration; may take into account whether the drug used is appropriate for the diagnosis as well as the outcome of pain treatment including improvement in patient functioning and/or quality of life; and will not assume that all types of pain can be completely relieved.

Section II: Treatment of Pain Practices
The Board recognizes that the medical community has encouraged the following practices as appropriate for the treatment of pain, including the use of controlled substances:

1. Evaluation of the Patient
A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan
The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment
The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

4. Periodic Review
The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers may be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

5. Consultation
The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records
The physician should keep accurate and complete records to include

- the medical history and physical examination;
- diagnostic, therapeutic and laboratory results;
- evaluations and consultations;
- treatment objectives;
- discussion of risks and benefits;
- informed consent;
- treatments;
- patient response to treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations
To prescribe, dispense or administer controlled substances, the physician must be licensed in Connecticut and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing controlled substances as well as applicable state statutes and regulations.

Section III: Definitions
For the purposes of this statement, the following terms are defined as follows:

(CONTINUED ON NEXT PAGE)

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Acute Pain
Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction
Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain
Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence
Physical dependence is a state of adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

CONNECTICUT

STATUTES

Health Care Institutions

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (training requirements) for health care institutions to ensure that pain management is an essential part of care of Alzheimer's patients.

Conn. Gen. Stat. § 19a-562a

§ 19a-562a. Alzheimer's special care units or programs. Direct care staff training requirements.

(a) Each Alzheimer's special care unit or program shall annually provide Alzheimer's and dementia specific training to all licensed and registered direct care staff and nurse's aides who provide direct patient care to residents enrolled in the Alzheimer's special care unit or program. Such requirements shall include, but not be limited to, (1) not less than eight hours of dementia-specific training, which shall be completed not later than six months after the date of employment and not less than three hours of such training annually thereafter, and (2) annual training of not less than two hours in pain recognition and administration of pain management techniques for direct care staff.

(b) Each Alzheimer's special care unit or program shall annually provide a minimum of one hour of Alzheimer's and dementia specific training to all unlicensed and unregistered staff, except nurse's aides, who provide services and care to residents enrolled in the Alzheimer's special care unit or program. For such staff hired on or after October 1, 2007, such training shall be completed not later than six months after the date of employment.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Licensure of Home Health Care Agencies

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes mechanisms for hospices to ensure that pain management is an essential part of patient care.

Regs., Conn. State Agencies § 19-13-D72

Sec. 19-13-D72. Patient care policies

(a) General Program Policies. An agency shall have written policies governing referrals received, admission of patients to agency services, delivery of such services and discharge of patients. Such policies shall cover all services provided by the agency, directly or under contract. A copy shall be readily available to patients and staff and shall include but not be limited to:

(B) An agency shall develop and implement written policies and procedures for all hospice services provided which include:

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(iii) Procedures for the provision of care and services to the patient family including advising the patient or legal representative of the nature of the palliative care offered. Palliative care includes pain control, symptom management, quality of life enhancement and spiritual and emotional comfort for patients and their caregivers; the patient's needs are continuously assessed and all treatment options are explored and evaluated in the context of the patient's values and symptoms;

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(vii) For hospice employees, six hours of the annual in-service education requirements in accordance with Section 19-13-D71(a)(2) of these regulations shall address topics related to hospice care. The agency shall ensure, as part of its coordination of inpatient care agreement with an inpatient setting, that all direct service staff receive in-service education including two hours specific to hospice care. The inservice education shall include current information regarding drugs and treatments, specific service procedures and techniques, pain and symptom management, psychosocial and spiritual aspects of care, interdisciplinary team approach to care, bereavement care, acceptable professional standards, and criteria and classification of clients served;

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(iii) The medical director's responsibilities shall include, but not be limited to:

II. Consultation with attending physicians regarding pain and symptom control and medical management as appropriate.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

DE

DELAWARE

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 16. Health and Safety; Part IV. Food and Drugs; Chapter 47. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Title 24. Professions and Occupations; Chapter 17. Medical Practice Act

- PHARMACY PRACTICE ACT
  Title 24. Professions and Occupations; Chapter 25. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Agency 16. Department of Health and Social Services; Sub-Agency 4000. Division of Public Health; Chapter 4426. Controlled Substances Act Regulations Health System Protection

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Agency 24. Department of State; Division of Professional Regulation. Sub-Agency 1700. Board of Medical Practice; Rules and Regulations

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Agency 24. Department of State; Division of Professional Regulation. Sub-Agency 2500. Board of Pharmacy; Rules and Regulations

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- DELIVERY OF HOSPICE SERVICES
  Agency 16. Department of Health and Social Services; Sub-Agency 4000. Division of Public Health; Chapter 4468. Delivery of Hospice Services; Health Systems Protection

DE

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act		●						
Pharmacy Practice Act			●					
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					●
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Delivery of Hospice Services								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances				•	•			
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Delivery of Hospice Services[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

DELAWARE

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

16 Del. C. § 4701

§ 4701. Definitions

As used in this chapter:

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(31) "Practitioner" means:

a. A physician, dentist, veterinarian, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this State.

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(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

24 Del. C. § 1702

§ 1702. Definitions

The following definitions apply to this chapter unless otherwise expressly stated or implied by the context.

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(9) "Practice of medicine" or "practice medicine" includes:

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c. Offering or undertaking to prevent or to diagnose, correct, and/or treat in any manner or by any means, methods, or devices a disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of another person, including the management of pregnancy and parturition;

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(+) *CRITERION 2:*
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

24 Del. C. § 2502

§ 2502. Definitions as used in this chapter

The following words, terms, and phrases when used in this chapter have the meanings ascribed to them in this section, except where the context clearly indicates a different meaning.

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(20) "Practitioner" or "prescriber" means any person who is authorized by law to prescribe drugs in the course of professional practice or research in any State.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

CDR 16-4000-4426

4.0 Prescriptions

4.1 Definitions. As used in this section:

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"Individual Practitioner" means physician, dentist, veterinarian, or other individual, licensed, registered, or otherwise permitted, by the United States or the State of Delaware to dispense a controlled substance in the course of professional practice but does not include a pharmacist, a pharmacy, or an institutional practitioner.

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CDR 16-4000-4426

4.8 Expiration of Prescription.

4.8.1 Prescriptions for controlled substances in Schedules II and III will become void unless dispensed within seven (7) days of the original date of the prescription or if the original prescriber authorizes the prescription past the seven (7) days period. Such prescriptions cannot be written nor dispensed for more than 100 dosage units or a 31 day supply whatever is the greater at one time. As an exception to dosage limitations set forth in this subparagraph, and in accordance with 21 C.F.R. Section 1306.1(b), prescriptions for controlled substances in Schedule II for patients either having a medically documented terminal illness or patients in Long Term Facilities (LTCF), may be filled in partial quantities, to include individual dosage units. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed.

4.8.2 Schedule II prescriptions for terminally ill or LTCF patients, shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the medication.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 13:*
Length of prescription validity is restricted

(-) *CRITERION 12:*
Medical decisions are restricted

***CATEGORY C*:**
Restrictions regarding quantity prescribed or dispensed

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Exemption of these patients nevertheless continues the prescribing restriction for all other patients.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Delivery of Hospice Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (interdisciplinary team) for hospices to ensure that pain management is an essential part of patient care.

CDR 16-4000-4468

16 4000 4468. DELIVERY OF HOSPICE SERVICES

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3.0 Hospice Care

3.1 Hospice is an option for care which utilizes an interdisciplinary team of the patient's choice. The team shall consist of at least a physician, nurse, social worker, clergy, trained volunteer, and the patient/family.

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3.3 The interdisciplinary team shall have the following responsibilities:

3.3.1 Perform an admission history which includes medical, social, spiritual, emotional aspects of the patient/family.

3.3.2 Develop the care plan for each patient/family. The patient care coordinator will be responsible for assuring the implementation and ongoing review of the care plan.

3.3.3 Hold an interdisciplinary care team meeting at least semimonthly or more often if needed to review and update the care plan.

3.3.4 Emphasize prevention and control of pain and other distressing symptoms.

3.3.5 Make provision for 24 hours per day, seven days a week coverage.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

DC

DISTRICT OF COLUMBIA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 48. Food and Drugs; Subtitle II. Prescription Drugs

- PROFESSIONAL PRACTICE ACT (*Relevant to both Medicine and Pharmacy*) (*No provisions found*)
  Title 3. District of Columbia Boards and Commissions; Subtitle 1. General; Chapter 12. Health Occupations Boards; Unit A. General

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 22. Public Health and Medicine
  Chapter 12. Controlled Substances Act Rules
  Chapter 13. Prescriptions and Distribution

- MEDICAL BOARD REGULATIONS
  Title 17. Business, Occupations, and Professions; Chapter 46. Medicine

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 17. Business, Occupations, and Professions; Chapter 65. Pharmacists

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- PROTECTION AND CARE SYSTEMS
  Title 7. Human Health Care and Safety; Subtitle I. Protection and Care Systems

DC

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Professional Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					
Medical Board		●	●				●	●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Protection and Care Systems		●						

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Professional Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances								●
Medical Board				●				
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Protection and Care Systems[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

D.C. Code § 48-901.02

§ 48-901.02. Definitions [Formerly § 33-501]

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(20) "Practitioner" means:

(A) A physician, dentist, advanced practice registered nurse, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in the District of Columbia; or.

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(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

DISTRICT OF COLUMBIA

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

D.C. Admin. Code § 22-1317.4

§ 22-1317.4 Administering or Dispensing of Narcotic Drugs

The rules of this chapter are not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Does this imply that opioids are a treatment of last resort?

CDCR 22-1399

22-1399. Definitions.

1399.1 As used in this chapter, the following words and phrases shall have the meanings ascribed:

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Individual Practitioner an individual who is licensed or registered in the District of Columbia to prescribe a prescription drug or medical device in the course of his or her professional practice, including a physician, dentist, veterinarian, podiatrist, optometrist, or advanced practice nurse. It does not include a pharmacist, pharmacy, or an institutional practitioner.

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(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

DISTRICT OF COLUMBIA

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

CDCR 17-4614

Section 17-4614. Standards for the Use of Controlled Substances for the Treatment of Pain

4614.1 A licensed physician shall prescribe, order, administer, or dispense controlled substances for pain only for a legitimate medical purpose based on accepted scientific knowledge of the treatment of pain or based on sound clinical grounds. All such prescribing shall be based on clear documentation of unrelieved pain and in compliance with applicable District or federal law.

4614.2 A licensed physician shall employ up-to-date treatment modalities in order to improve the quality of life for patients who suffer from pain as well as to reduce the morbidity and costs incurred by patients associated with untreated or inappropriately treated pain. For purposes of this section, "inappropriately treated pain" includes the following:

(a) Non-treatment;

(b) Under-treatment;

(c) Over-treatment; and

(d) The continued use of ineffective treatments.

4614.3 A licensed physician shall perform an evaluation of the patient by taking a complete medical history and performing a physical examination. The medical history and physical examination shall be documented in the medical record. The medical record shall contain a description of the following:

(a) The nature and intensity of the patient's pain;

(b) The patient's current and past treatments for pain;

(c) The patient's underlying or coexisting diseases or conditions;

(d) The effect of the pain on the patient's physical and psychological function;

(e) A history of the patient's substance abuse if applicable; and

(f) The presence of one or more recognized medical indications in the patient for the use of a controlled substance.

4614.4 A licensed physician shall maintain a written treatment plan which states the objectives used to determine treatment success, such as pain relief and improved physical and psychosocial function

4614.5 The treatment plan shall indicate if any further diagnostic evaluations or other treatments are planned.

4614.6 The physician shall adjust drug therapy to the individual medical needs of each patient after treatment begins.

4614.7 The physician shall consider other treatment modalities or a rehabilitation program if necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

4614.8 The physician shall discuss the risks and benefits of the use of controlled substances with the patient, person(s) designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

DISTRICT OF COLUMBIA

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

4614.9 If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician shall employ the use of a written agreement between the physician and patient outlining the patient's responsibilities, including, but not limited to:

(a) Urine/serum medication levels screening when requested;

(b) Number and frequency of all prescription refills; and

(c) Reasons for which drug therapy may be discontinued, such as violation of an agreement.

4614.10 The physician shall do the following:

(a) Review the course of treatment and any new information about the etiology of the pain at reasonable intervals based on the individual circumstances of the patient;

(b) Continue or modify the pain therapy depending on the physician's evaluation of the patient's progress;

(c) Reevaluate the appropriateness of continued treatment if treatment goals are not being achieved despite medication adjustments; and

(d) Monitor the patient's compliance in medication usage and and related treatment plans.

4614.11 The physician shall refer the patient, as necessary, to another physician for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion.

4614.12 The physician shall consult with or refer to an expert for management the following types of patients:

(a) Patients with a history of substance abuse; or

(b) Patients with comorbid psychiatric disorders that require extra care, monitoring, and documentation.

4614.13 The physician shall recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

4614.14 The physician shall keep accurate and complete records that include, but are not limited to:

(a) The medical history and physical examination, including history of drug abuse or dependence, as appropriate;

(b) Diagnostic, therapeutic, and laboratory results;

(c) Evaluations and consultations;

(c) Treatment objectives;

(d) Discussion of risks and benefits;

(e) Treatments;

(f) Medications including date, type, dosage, and quantity prescribed;

(g) Instructions and agreements; and

(h) Periodic reviews.

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY B:
Mandated consultation

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

DISTRICT OF COLUMBIA

STATUTES

Protection and Care Systems

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

D.C. Code § 7-2071.01

§ 7-2071.01. Definitions

For the purposes of this chapter, the term:

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(8) "Health care services" means items or services provided under the supervision of a physician or other person trained or licensed to render health care necessary for the prevention, care, diagnosis, or treatment of human disease, pain, injury, deformity, or other physical or mental condition, including the following: pre-admission, outpatient, inpatient, and post-discharge care; home care; physician's care; nursing care; medical care provided by interns or residents in training; other paramedical care; ambulance service and care; bed and board; drugs; supplies; appliances; equipment; laboratory services; any form of diagnostic imaging or therapeutic radiological services; and services mandated under Chapter 31 of Title 31.

(+) *CRITERION 2:*
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

FLORIDA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 46. Crimes; Chapter 893. Drug Abuse Prevention and Control

- MEDICAL PRACTICE ACT
  Title 32. Regulation of Professions and Occupations; Chapter 458. Medical Practice

- OSTEOPATHIC PRACTICE ACT
  Title 32. Regulation of Professions and Occupations; Chapter 459. Osteopathic Medicine

- PHARMACY PRACTICE ACT
  Title 32. Regulation of Professions and Occupations; Chapter 465. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Title 64. Department of Health; 64F. Division of Family Health Services; Chapter 64F-12. Regulations for Drugs, Devices and Cosmetics

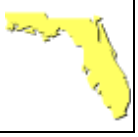
- MEDICAL BOARD REGULATIONS
  Title 64. Department of Health; 64B8. Board of Medicine

- OSTEOPATHIC BOARD REGULATIONS
  Title 64. Department of Health; 64B15. Board of Osteopathic Medicine

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 64. Department of Health; 64B16. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- JOINT BOARD POLICY STATEMENT
  Florida Boards of Medicine, Nursing, Osteopathic Medicine, and Pharmacy. *Joint Statement on Pain Management: Florida Boards of Medicine, Nursing, Osteopathic Medicine, and Pharmacy*. Adopted: September 19, 2005.



RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- CHILDREN'S MEDICAL SERVICES
  Title 29. Public Health; Chapter 391. Children's Medical Services; Part I. General Provisions

- HOSPICES
  Title 29. Public Health; Chapter 400. Nursing Homes and Related Health Care Facilities; Part VI. Hospices

- CIVIL RIGHTS
  Title 44. Civil Rights; Chapter 765. Health Care Advanced Directives; Part 1. General Provisions

- HOSPICE SERVICES
  Title 58. Department of Elder Affairs; Chapter 58A-2. Hospice

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act		●	●					
Osteopathic Practice Act		●						
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board		●	●	●	●	●	●	●
Osteopathic Board		●	●	●	●	●	●	●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Joint Board Policy Statement		●		●				●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Children's Medical Services		●						
Hospices								●
Civil Rights								●
Hospice Services								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act		●						●
Osteopathic Practice Act								●
Pharmacy Practice Act								●
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Osteopathic Board[1]								
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Children's Medical Services[1]								
Hospices[1]								
Civil Rights[1]								
Hospice Services[1]								

Note: A dot indicates that one or more provisions were identified
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STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Fla. Stat. § 893.13

§ 893.13. Prohibited acts; penalties

(1) (a) Except as authorized by this chapter and chapter 499, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance...

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(9) The provisions of subsections (1)-(8) are not applicable to the delivery to, or actual or constructive possession for medical or scientific use or purpose only of controlled substances by, persons included in any of the following classes, or the agents or employees of such persons, for use in the usual course of their business or profession or in the performance of their official duties:

(a) Pharmacists.

(b) Practitioners.

(c) Persons who procure controlled substances in good faith and in the course of professional practice only, by or under the supervision of pharmacists or practitioners employed by them, or for the purpose of lawful research, teaching, or testing, and not for resale.

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(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Fla. Stat. § 458.305

458.305 Definitions.

As used in this chapter:

(1) "Board" means the Board of Medicine.

(2) "Department" means the Department of Health.

(3) "Practice of medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.

(4) "Physician" means a person who is licensed to practice medicine in this state.

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(+) *CRITERION 2:*
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 10:*
Implies opioids are not part of professional practice

Fla. Stat. § 458.326

§ 458.326. Intractable pain; authorized treatment

(1) For the purposes of this section, the term "intractable pain" means pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated.

(2) Intractable pain must be diagnosed by a physician licensed under this chapter and qualified by experience to render such diagnosis.

(3) Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II-V, as provided for in *s. 893.03*, to a person for the treatment of intractable pain, provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances.

(4) Nothing in this section shall be construed to condone, authorize, or approve mercy killing or euthanasia, and no treatment authorized by this section may be used for such purpose.

(+) *CRITERION 3:*
Opioids are part of professional practice

Fla. Stat. § 458.331

458.331 Grounds for disciplinary action; action by the board and department.

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

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(q) Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician's professional practice. For the purposes of this paragraph, it shall be legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT:
"Inappropriate" and "excessive" implies there is a limit, but the limit is not specified. Also, elimination of the critically important intent of the physician in deciding cases appears to add to the uncertainty of how this provision might be interpreted.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Osteopathic Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

Fla. Stat. § 459.003

§ 459.003. Definitions

As used in this chapter:

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(3) "Practice of osteopathic medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition, which practice is based in part upon educational standards and requirements which emphasize the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health.

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§ 459.015. Grounds for disciplinary action; action by the board and department

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in *s. 456.072(2)*:

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(t) Prescribing, dispensing, administering, supplying, selling, giving, mixing, or otherwise preparing a legend drug, including all controlled substances, other than in the course of the osteopathic physician's professional practice. For the purposes of this paragraph, it shall be legally presumed that prescribing, dispensing, administering, supplying, selling, giving, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the osteopathic physician's professional practice, without regard to his or her intent.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: "Inappropriate" and "excessive" implies there is a limit, but the limit is not specified. Also, elimination of the critically important intent of the physician in deciding cases appears to add to the uncertainty of how this provision might be interpreted.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: "Excessive" and "inappropriate" implies there is a limit, but the limit is not specified.

Fla. Stat. § 465.016

465.016 Disciplinary actions.

(1) The following acts shall be grounds for disciplinary action set forth in this section:

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(i) Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. For purposes of this paragraph, it shall be legally presumed that the compounding, dispensing, or distributing of legend drugs in excessive or inappropriate quantities is not in the best interests of the patient and is not in the course of the professional practice of pharmacy.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

64B8-9.013, F.A.C.

64B8-9.013 Standards for the Use of Controlled Substances for Treatment of Pain.

(1) Pain management principles.

(a) The Board of Medicine recognizes that principles of quality medical practice dictate that the people of the State of Florida have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from physicians lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances including opioid analgesics, for a legitimate medical purpose and that is supported by appropriate documentation establishing a valid medical need and treatment plan. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the U.S. Agency for Health Care Policy and Research Clinical Practical Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain including intractable pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board of Medicine is obligated under the laws of the State of Florida to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(e) The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

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(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

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(g) The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(2) Definitions.

(a) Acute Pain. For the purpose of this rule, acute pain is defined as the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma, and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

(b) Addiction. For the purpose of this rule, addiction is defined as a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as drug dependence and psychological dependence. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(c) Analgesic Tolerance. For the purpose of this rule, analgesic tolerance is defined as the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(d) Chronic Pain. For the purpose of this rule, chronic pain is defined as a pain state which is persistent.

(e) Pain. For the purpose of this rule, pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(f) Physical Dependence. For the purpose of this rule, physical dependence on a controlled substance is defined as a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(g) Pseudoaddiction. For the purpose of this rule, pseudoaddiction is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) Substance Abuse. For the purpose of this rule, substance abuse is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(i) Tolerance. For the purpose of this rule, tolerance is defined as a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

(3) Guidelines. The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(c) Informed Consent and Agreement for Treatment. The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:

1. urine/serum medication levels screening when requested;
2. number and frequency of all prescription refills; and
3. reasons for which drug therapy may be discontinued (i.e., violation of agreement).

(d) Periodic Review. At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

(e) Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

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REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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(f) Medical Records. The physician is required to keep accurate and complete records to include, but not be limited to:

1. the medical history and physical examination;
2. diagnostic, therapeutic, and laboratory results;
3. evaluations and consultations;
4. treatment objectives;
5. discussion of risks and benefits;
6. treatments;
7. medications (including date, type, dosage, and quantity prescribed);
8. instructions and agreements; and
9. periodic reviews.

Records must remain current and be maintained in an accessible manner and readily available for review.

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual: An Informational Outline of the Controlled Substances Act of 1970, published by the U.S. Drug Enforcement Agency, for specific rules governing controlled substances as well as applicable state regulations.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Osteopathic Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

64B15-14.005, F.A.C.

64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain.

(1) Pain management principles.

(a) The Board of Osteopathic Medicine recognizes that principles of quality medical practice dictate that the people of the State of Florida have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages osteopathic physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All osteopathic physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from an osteopathic physician's lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Osteopathic physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances including opioid analgesics, for a legitimate medical purpose and that is supported by appropriate documentation establishing a valid medical need and treatment plan. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

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(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Osteopathic Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Osteopathic physicians are referred to the U.S. Agency for Health Care Policy and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain including intractable pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Osteopathic physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board of Osteopathic Medicine is obligated under the laws of the State of Florida to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Osteopathic physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(e) The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against an osteopathic physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The osteopathic physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

(g) The Board will judge the validity of prescribing based on the osteopathic physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(2) Definitions.

(a) Acute Pain. For the purpose of this rule, "acute pain" is defined as the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma, and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

(b) Addiction. For the purpose of this rule, "addiction" is defined as a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

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(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Osteopathic Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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(c) Analgesic Tolerance. For the purpose of this rule, "analgesic tolerance" is defined as the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(d) Chronic Pain. For the purpose of this rule, "chronic pain" is defined as a pain state which is persistent.

(e) Pain. For the purpose of this rule, "pain" is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(f) Physical Dependence. For the purpose of this rule, "physical dependence" on a controlled substance is defined as a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(g) Pseudoaddiction. For the purpose of this rule, "pseudoaddiction" is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) Substance Abuse. For the purpose of this rule, "substance abuse" is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(i) Tolerance. For the purpose of this rule, "tolerance" is defined as a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

(3) Guidelines. The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the osteopathic physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(c) Informed Consent and Agreement for Treatment. The osteopathic physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one osteopathic physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the osteopathic physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Osteopathic Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

1. Urine/serum medication levels screening when requested;

2. Number and frequency of all prescription refills; and

3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).

(d) Periodic Review. At reasonable intervals based on the individual circumstances of the patient, the osteopathic physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the osteopathic physician's evaluation of progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the osteopathic physician should reevaluate the appropriateness of continued treatment. The osteopathic physician should monitor patient compliance in medication usage and related treatment plans.

(e) Consultation. The osteopathic physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

(f) Medical Records. The osteopathic physician is required to keep accurate and complete records to include, but not be limited to:

1. The medical history and physical examination;

2. Diagnostic, therapeutic, and laboratory results;

3. Evaluations and consultations;

4. Treatment objectives;

5. Discussion of risks and benefits;

6. Treatments;

7. Medications (including date, type, dosage, and quantity prescribed);

8. Instructions and agreements; and

9. Periodic reviews.

Records must remain current and be maintained in an accessible manner and readily available for review.

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense, or administer controlled substances, the osteopathic physician must be licensed in the state and comply with applicable federal and state regulations. Osteopathic physicians are referred to the Physicians Manual: An Informational Outline of the Controlled Substances Act of 1970, published by the U.S. Drug Enforcement Agency, for specific rules governing controlled substances as well as applicable state regulations.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

The Florida Boards of Medicine, Nursing, Osteopathic Medicine, and Pharmacy recognize that principles of quality medical practice dictate that the people of the state of Florida have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain; including non-treatment, under-treatment, over-treatment, and the continued use of ineffective treatments.

It is, therefore, incumbent upon Florida physicians, nurses and pharmacists to work cooperatively and effectively to address the dimensions of pain and to provide maximum pain relief with minimal side effects. Towards that end, and in the interest of public protection, the Florida Boards of Medical Practice, Nursing and Pharmacy issue the following joint statement.

To effectively assist patients in the management of pain, health care professionals should, within their scope of practice:

- Consistently and thoroughly assess all patients for pain. If pain is reported, the pain should be evaluated with a complete history and physical with laboratory and diagnostic testing, if indicated;
- Work collaboratively in a multi-disciplinary approach to develop and implement an individualized, written treatment plan utilizing pharmacologic and non-pharmacologic interventions with specific objectives for the patient;
- Regularly evaluate the effectiveness of the treatment plan, using a consistent, developmentally appropriate, standardized pain scale, and make adjustments as needed;
- Document all aspects of pain assessment and care in a timely, clear, consistent, complete and accurate manner;
- Anticipate and effectively manage side effects of pain medications;
- Provide adequate and culturally appropriate information to patients and family members or caregivers to support patients in making informed decisions and participate in the management of their pain;
- Be aware of the risks of diversion and abuse of controlled substances and take appropriate steps to minimize these risks;
- Recognize individuals with chemical dependency may experience pain requiring medications, including opioids, and may require specialized management;
- Consult with, and refer patients to, other providers when appropriate;
- Develop organization-appropriate and evidence-based policies and protocols for pain management;
- Become and remain knowledgeable regarding effective pain management; and
- Comply with all state and federal laws and regulations regarding prescribing, dispensing, and administering legend drugs, including controlled substances.

The Florida Boards of Medicine, Nursing, Osteopathic Medicine, and Pharmacy also recognize that concerns of drug diversion hinders quality medical practice and access to appropriate effective pain relief for the citizens of the state of Florida.

Towards that end and in the interest of public protection, the Florida Boards of Medicine, Osteopathic Medicine, Nursing and Pharmacy issue the following joint statement.

To effectively assist health care practitioners in the management of patient pain care and in order to effectively address prescription drug diversion the state of Florida must:

Develop a statewide electronic controlled substance prescription monitoring system that could be used by practitioners to assist them in treating patient pain as well as drug abuse.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

(+) *CRITERION 4:*
Pain management is encouraged

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes a practitioner's responsibility to provide patients information about pain management and palliative care when considering treatment options.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Identifies concerns of drug diversion as an important barrier to access to appropriate pain relief.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

STATUTES

Children's Medical Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Fla. Stat. § 391.021

§ 391.021. Definitions

When used in this act, unless the context clearly indicates otherwise:

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(6) "Health services" includes the prevention, diagnosis, and treatment of human disease, pain, injury, deformity, or disabling conditions.

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(+) *CRITERION 2:*
Pain management is part of medical practice

STATUTES

Hospices

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (outcome measures) for hospices to ensure that pain management is an essential part of patient care.

Fla. Stat. § 400.60501

§ 400.60501. Outcome measures; adoption of national initiatives; annual report

(1) No later than December 31, 2007, the Department of Elderly Affairs, in conjunction with the Agency for Health Care Administration, shall develop outcome measures to determine the quality and effectiveness of hospice care for hospices licensed in the state. At a minimum, these outcome measures shall include a requirement that 50 percent of patients who report severe pain on a 0-to-10 scale must report a reduction to 5 or less by the end of the 4th day of care on the hospice program.

(2) For hospices licensed in the state, the Department of Elderly Affairs, in conjunction with the Agency for Health Care Administration, shall:

(a) Consider and adopt national initiatives, such as those developed by the National Hospice and Palliative Care Organization, to set benchmarks for measuring the quality of hospice care provided in the state.

(b) Develop an annual report that analyzes and evaluates the information collected under this act and any other data collection or reporting provisions of law.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Civil Rights

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (standards and guidelines and continuing education) to provide practitioners information/education about pain management and palliative care.

Fla. Stat. § 765.102

§ 765.102. Legislative findings and intent

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(4) The Legislature recognizes the need for all health care professionals to rapidly increase their understanding of end-of-life and palliative care. Therefore, the Legislature encourages the professional regulatory boards to adopt appropriate standards and guidelines regarding end-of-life care and pain management and encourages educational institutions established to train health care professionals and allied health professionals to implement curricula to train such professionals to provide end-of-life care, including pain management and palliative care.

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§ 765.1103. Pain management and palliative care

(1) A patient shall be given information concerning pain management and palliative care when he or she discusses with the attending or treating physician, or such physician's designee, the diagnosis, planned course of treatment, alternatives, risks, or prognosis for his or her illness. If the patient is incapacitated, the information shall be given to the patient's health care surrogate or proxy, court-appointed guardian as provided in chapter 744, or attorney in fact under a durable power of attorney as provided in chapter 709. The court-appointed guardian or attorney in fact must have been delegated authority to make health care decisions on behalf of the patient.

(2) Health care providers and practitioners regulated under chapter 458, chapter 459, or chapter 464 must, as appropriate, comply with a request for pain management or palliative care from a patient under their care or, for an incapacitated patient under their care, from a surrogate, proxy, guardian, or other representative permitted to make health care decisions for the incapacitated patient. Facilities regulated under chapter 395, chapter 400, or chapter 429 must comply with the pain management or palliative care measures ordered by the patient's physician.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Establishes a responsibility for practitioners to try to comply with patients' requests for pain management or palliative care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes a practitioner's responsibility to provide patients information about pain management and palliative care when considering treatment options.

REGULATIONS

Hospice Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

58A-2.014, F.A.C.

58A-2.014 Medical Direction.

(1) The hospice shall employ a medical director who shall be a hospice physician licensed in the State of Florida pursuant to Chapter 458 or 459, F.S., who has admission privileges at one or more hospitals commonly serving patients in that hospice's service area as defined in Rule *59C-1.0355, F.A.C.* Duties shall be enumerated in a job description, including job qualifications, which shall be kept in an administrative file.

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(b) Duties of the medical director shall include:

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9. Establishing written protocols for symptom control, i.e., pain, nausea, vomiting, or other symptoms.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written protocols) for hospices to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

GA

GEORGIA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 16. Crimes and Offenses; Chapter 13. Controlled Substances

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 43. Professions and Businesses; Chapter 34. Physicians, Acupuncture, Physician's Assistants, Cancer and Glaucoma Treatment, Respiratory Care, Clinical Perfusionists, and Orthotics and Prosthetics Practice; Article 2. Physicians

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 26. Food, Drugs, and Cosmetics; Chapter 4. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Title 480. Georgia State Board of Pharmacy; Chapter 480-34. Controlled Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 360. Composite State Board of Medical Examiners

- PHARMACY BOARD REGULATIONS
  Title 480. Georgia State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Georgia Composite State Board of Medical Examiners. *Guidelines for the Use of Controlled Substances for the Treatment of Pain: Ten Steps*. Adopted: January 11, 2008.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HOSPICE SERVICES
  Title 290. Department of Human Resources Office of Regulatory Services; Chapter 290-9-43. Rules and Regulations for Hospices

GA

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board			●					
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Services								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Services[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

O.C.G.A. § 16-13-21

§ 16-13-21. Definitions

As used in this article, the term:

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(8) "Dependent," "dependency," "physical dependency," "psychological dependency," or "psychic dependency" means and includes the state of dependence by an individual toward or upon a substance, arising from the use of that substance, being characterized by behavioral and other responses which include the loss of self-control with respect to that substance, or a strong compulsion to use that substance on a continuous basis in order to experience some psychic effect resulting from the use of that substance by that individual, or to avoid any discomfort occurring when the individual does not use that substance.

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(23) "Practitioner" means:

(A) A physician, dentist, pharmacist, podiatrist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise authorized under the laws of this state to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state;

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(-) *CRITERION 11:* *Physical dependence or analgesic tolerance confused with "addiction"*

(+) *CRITERION 3:* *Opioids are part of professional practice*

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Ga. Comp. R. & Regs. r. 480-22-.14

480-22-.14 Ordering and Receipt of Samples.

(1) For purposes of this rule, a practitioner means:

(a) A physician, dentist, podiatrist, veterinarian, or other person licensed, registered, or otherwise authorized under the laws of this state to distribute, dispense, with respect to, or to administer a controlled substance or dangerous drug in the course of professional practice in this state;

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(+) *CRITERION 3:* *Opioids are part of professional practice*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

GEORGIA COMPOSITE STATE BOARD OF MEDICAL EXAMINERS

Guidelines for the Use of Controlled Substances for the Treatment of Pain: Ten Steps

Disclaimer
These guidelines are primarily intended to provide orientation for physicians intending to prescribe schedule II and III analgesics for the purpose of treating chronic pain conditions and do not necessarily apply to clinical conditions where rapid adjustments in medical management are required such as acute pain management following surgery, emergency care pain management and end-of-life care.

The Georgia Composite State Board of Medical Examiners (the Medical Board) recognizes that principles of quality medical practice dictate that the people of the state of Georgia have access to appropriate and effective pain relief by licensed physicians. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of these guidelines, the inappropriate treatment of pain includes no treatment, under treatment, over treatment, and the continued use of ineffective treatments.

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 2:*
Pain management is part of medical practice

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as an essential part of quality medical practice for all patients with pain, including both acute and chronic disease. All physicians should be or seek to become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as becoming familiar with statutory requirements for prescribing controlled substances. These guidelines have been developed to clarify the Board's position on pain management, particularly as it relates to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management practices. The guidelines are also intended to curtail drug diversion, a serious public safety concern for the Board and law enforcement agencies.

(+) *CRITERION 4:*
Encourages pain management

Adherence to the guidelines outlined here will not only improve quality medical practice but will also improve the board's efficiency in its investigations by distinguishing legitimate practice from foul play.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice.

To prevent any misunderstanding, it is necessary to state what the Board does not have. The Board does not have a list of "bad" or "disallowed" drugs. All formulary drugs are generally effective if prescribed and administered when properly indicated. Conversely, drugs are potentially ineffective, dangerous, or even lethal when used inappropriately.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

The Board does not have a "magic formula" for determining the dosage and duration of administration for any drug. These are aspects of prescribing that must be determined within the confines of the individual clinical case and continued under proper monitoring. What is good for one patient may be insufficient or fatal for another.

The Board does have the expectation that physicians will create a record that shows evaluation of every patient receiving a controlled substance prescription as follows:

Proper indication for the use of drug or other therapy
Monitoring of the patient where necessary
The patient's response to therapy on follow-up visits
All rationale for continuing or modifying the therapy
Discussion of risks/benefits
Periodic medical record review
Prescription records

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

STEP ONE

A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance. Perform a workup sufficient to support a diagnosis including all necessary tests, history and physical examination. If medical testing is negative, carefully document the rationale of therapy and its effectiveness. When a diagnosis is undetermined, despite the complaint of severe pain, consider consultation for further analysis. The medical record will need to document sufficient and appropriate H&P and diagnostic testing to support the diagnosis necessitating the use of controlled substances.

STEP TWO

Create a treatment plan, which includes the use of appropriate non-controlled drugs, and consider referrals to appropriate specialists, such as neurologists, orthopedists, pain management specialists, addictionologists, psychiatrists, etc. The result of the referral should be included in the patient's chart. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned.

STEP THREE

Before beginning a regimen of controlled drugs, make a determination through trial or through a documented history and physical that non-controlled drugs are not appropriate or effective for the patient's condition. The above does NOT apply to acutely painful conditions such as an acute injury or surgery, nor does it apply to the management of pain in cancer or hospice patients. It may also not apply for patients who have a contraindication to, or are at high risk of experiencing side effects from non-steroidal anti-inflammatory drugs such as the elderly.

Although non-controlled drugs (e.g., aspirin, acetaminophen, NSAIDS) often are adequate to treat painful conditions of mild severity, the Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. This does not mean that opioids and other controlled substances cannot be used as a first-line therapy, but it is important to document the rationale when used as such.

STEP FOUR

Review the patient's prescription records and discuss the patient's chemical history before prescribing a controlled drug. If the patient is new or otherwise unknown to you, at a minimum obtain an oral drug history and medication allergies, and discuss chemical use and family chemical history with the patient and obtain old records which may include pharmacy records.

STEP FIVE

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient does not have decision making capacity. The physician must remain in compliance with HIPAA regulations. Take the time to explain the relative risks and benefits of the drug and record in the chart the fact that this was done. When embarking on what appears to be the long-term use of a dependence-causing or potentially addictive substance, it may be wise to hold a family conference and explain differences between physical dependence, tolerance and addiction.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that controlled substances can be used as a first-line therapy when there is medical justification (e.g., severe chronic pain).

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

STEP SIX

Maintain regular monitoring of the patient, including frequent physical monitoring. If the regimen is for prolonged need for the drug use it is very important to monitor the patient for the underlying condition which necessitates the drug and for the side effects of the drug itself. This is true no matter what type of controlled substance is used or to what schedule it belongs. It is very important to monitor the patient for the underlying condition which necessitates the use of controlled substances. It is also important to monitor the patient for side effects that may occur with the use of the selected controlled substance(s).

STEP SEVEN

The physician must keep detailed records of the type, dosage and amount of the drug prescribed. Prescribing physicians should also monitor and personally control all refills. One good way to accomplish this is to require the patient to return to obtain refill authorization, at least part of the time. Records of the cumulative dosage and average daily dosage are especially valuable. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities and checking on whether the patient is obtaining drugs from other physicians. Checking with pharmacies may indicate a patient is obtaining additional drugs or is doctor shopping. It is a felony in Georgia for a patient to fail to disclose to his physician that he has received controlled substances of a similar therapeutic use from another practitioner at the same time. If you are aware of these situations occurring, contact your local police or the Georgia Drug and Narcotics Agency.

STEP EIGHT

With the patient's permission, the patient's family may be a valuable source of information on the patient's response to the therapy regimen and the patient's functional status, and may provide more accurate and objective feedback than the patient alone.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Family may be a much better source of information on behavioral changes, especially dysfunctional behavior, than is the patient. Dysfunctional changes may be observable when the patient is taking the drug, or when the drug is discontinued. These changes, at the time, may be symptoms of dependency or addiction. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

STEP NINE

Maintaining adequate records is extremely important. The physician who carefully manages pain treatment and maintains detailed records which reflect all the steps involved in the process will be able to assess and review the treatment course and progress.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

STEP TEN

Document
Document
Document
Keep accurate and complete records to include:
The medical history and physical examination
Diagnostic, therapeutic and laboratory results
Evaluations and consultations
Treatment objectives
Medications (including date, type, dosage and quantity prescribed)
Instructions and agreements, pain contracts (where applicable)

Definitions:

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospice Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (systematic reviews) for hospices to ensure that pain management is an essential part of patient care.

Ga. Comp. R. & Regs. r. 290-9-43-.09

290-9-43-.09 Quality Management.

(1) The hospice shall appoint a multidisciplinary quality management committee that reflects the hospice's scope of services. The committee shall develop and implement a comprehensive and ongoing quality management, utilization, and peer review program that evaluates the quality and appropriateness of patient care provided, including the appropriateness of the level of service received by patients, and submits required patient incident reports to the Department.

(2) The quality management, utilization, and peer review program shall establish and use written criteria as the basis to evaluate the provision of patient care. The written criteria shall be based on accepted standards of care and shall include, at a minimum, systematic reviews of:

(a) Appropriateness of admissions, continued stay, and discharge;

(b) Appropriateness of professional services and level of care provided;

(c) Effectiveness of pain control and symptom relief;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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HAWAII

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Division 1. Government; Title 19. Health; Chapter 329. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Division 2. Business; Title 25. Professions and Occupations; Chapter 453. Medicine and Surgery

- OSTEOPATHIC PRACTICE ACT
  Division 2. Business; Title 25. Professions and Occupations; Chapter 460. Osteopathy

- PHARMACY PRACTICE ACT (*No provisions found*)
  Division 2. Business; Title 25. Professions and Occupations; Chapter 461. Pharmacists and Pharmacy

- PAIN PATIENT'S BILL OF RIGHTS
  Division 1. Government; Title 19. Health; Chapter 327H. Pain Patient's Bill of Rights

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 23. Department of Public Safety; Subtitle 3. Law Enforcement; Chapter 200. Regulation of Controlled Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 16. Department of Commerce and Consumer Affairs; Chapter 85. Medical Examiners

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Title 16. Department of Commerce and Consumer Affairs; Chapter 93. Osteopaths

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 16. Department of Commerce and Consumer Affairs; Chapter 95. Pharmacists and Pharmacies

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Hawaii Board of Medical Examiners. *Hawaii Board of Medical Examiners Pain Management Guidelines*. Adopted: January, 2006.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

No policies found

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act								●
Osteopathic Practice Act								●
Pharmacy Practice Act[1]								
Pain Patient's Bill of Rights		●		●				●
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●		●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES[2]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act			●		●			
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Pain Patient's Bill of Rights								●
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances					●			
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES[2]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

HAWAII

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

HRS § 329-1

§ 329-1. Definitions.

As used in this chapter:

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"Practitioner" means: (1) A physician, dentist, veterinarian, scientific investigator, or other person licensed and registered under section 329-32 to distribute, dispense, or conduct research with respect to a controlled substance in the course of professional practice or research in this State.

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HRS § 329-38

§ 329-38. Prescriptions.

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(b) A schedule II controlled substance prescription shall:

(1) Be filled within three days following the date the prescription was issued to the patient; and

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HRS § 329-40

§ 329-40. Methadone treatment programs

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The term "narcotic-dependent person" as used in this section means an individual who physiologically needs heroin or a morphine-like drug to prevent the onset of signs of withdrawal.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 13:*
Length of prescription validity is restricted

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

HRS § 453-1.5

453-1.5. Pain management guidelines.

The board of medical examiners may establish guidelines for physicians with respect to patients' pain management. The guidelines shall apply to all patients with severe acute pain or severe chronic pain, regardless of the patient's prior or current chemical dependency or addiction, and may include standards and procedures for chemically dependent individuals.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (guidelines) for the board to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Osteopathic Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (guidelines) for the board to ensure that pain management is an essential part of patient care.

HRS § 460-1.35

[460-1.35.] Pain management guidelines.

The board of medical examiners may establish guidelines for osteopathic physicians with respect to patients' pain management. The guidelines shall apply to all patients with severe acute pain or severe chronic pain, regardless of the patient's prior or current chemical dependency or addiction, and may include standards and procedures for chemically dependent individuals.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

STATUTES

Pain Patient's Bill of Rights

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

HRS prec § 327H-1 – § 327H-2

[§ 327H-1.] Pain patient's bill of rights; findings.

The legislature finds that:

(1) Inadequate treatment of severe acute pain and severe chronic pain originating from cancer or noncancerous conditions is a significant health problem;

(2) For some patients, pain management is the single most important treatment a physician can provide;

(3) A patient who suffers from severe acute pain or severe chronic pain should have access to proper treatment of pain;

(4) Due to the complexity of their problems, many patients who suffer from severe acute pain or severe chronic pain may require referral to a physician with expertise in the treatment of severe acute pain and severe chronic pain. In some cases, severe acute pain and severe chronic pain is best treated by a team of clinicians to address the associated physical, psychological, social, and vocational issues;

(5) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute pain or severe chronic pain can be safe; and

(6) Opiates may be part of an overall treatment plan for a patient in severe acute pain or severe chronic pain who has not obtained relief from any other means of treatment.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pain Patient's Bill of Rights

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes the patient's right to request or reject different types of treatments.

[CONTINUED]

[§ 327H-2.] Bill of rights.

The pain patient's bill of rights includes the following:

(1) A patient who suffers from severe acute pain or severe chronic pain has the option to request or reject the use of any or all modalities to relieve the pain;

(2) A patient who suffers from severe acute pain or severe chronic pain has the option to choose from appropriate pharmacologic treatment options to relieve severe acute pain or severe chronic pain, including opiate medications, without first having to submit to an invasive medical procedure.

For purposes of this paragraph, "invasive medical procedure" means surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device;

(3) A patient's physician may refuse to prescribe opiate medication for a patient who requests a treatment for severe acute pain or severe chronic pain. However, that physician may inform the patient of physicians who are qualified to treat severe acute pain and severe chronic pain employing methods that include the use of opiates;

(4) A physician who uses opiate therapy to relieve severe acute pain or severe chronic pain may prescribe a dosage deemed medically necessary to relieve the pain;

(5) A patient may voluntarily request that the patient's physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification; and

(6) Nothing in this section shall be construed to:

(A) Expand the authorized scope of practice of any licensed physician;

(B) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices; and

(C) Prohibit the discipline or prosecution of a licensed physician for:

(i) Failing to maintain complete, accurate, and current records that document the physical examination and medical history of a patient, the basis for the clinical diagnosis of a patient, and the treatment plan for a patient;

(ii) Writing false or fictitious prescriptions for controlled substances scheduled in the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, *21 U.S.C. 801* et seq. or in chapter 329;

(iii) Prescribing, administering, or dispensing pharmaceuticals in violation of the provisions of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, *21 U.S.C. 801* et seq. or of chapter 329;

(iv) Diverting medications prescribed for a patient to the licensed physician's own personal use; and

(v) Causing, or assisting in causing, the suicide, euthanasia, or mercy killing of any individual; provided that it is not "causing, or assisting in causing, the suicide, euthanasia, or mercy killing of any individual" to prescribe, dispense, or administer medical treatment for the purpose of treating severe acute pain or severe chronic pain, even if the medical treatment may increase the risk of death, so long as the medical treatment is not also furnished for the purpose of causing, or the purpose of assisting in causing, death for any reason.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: How does this qualify as a "Pain Patient's Bill of Rights"? This language falls short of providing any rights to specific treatment and may establish a false expectation for adequate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

WCHR 23-200

23-200. REGULATION OF CONTROLLED SUBSTANCES

§ 23-200-2 Definitions. The following definitions shall apply in the interpretation and enforcement of this chapter:

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"Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator, or other person licensed and registered under *section 329-32, Hawaii Revised Statutes*, to distribute, dispense, prescribe or conduct research with respect to a controlled substance in the course of professional practice or research in this State but does not include midlevel practitioners.

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§ 23-200-15 Prescriptions.

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(2) No prescription for a schedule II controlled substance shall be filled later than the third day following the day of issuance;

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 13:*
Length of prescription validity is restricted

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Pursuant to section 453-1.5, Hawaii Revised Statutes, the Board of Medical Examiners ("Board") has established guidelines for physicians with respect to the care and treatment of patients with severe acute pain or severe chronic pain. These pain management guidelines are considerations that the Board will take into account in the proper treatment of pain.

HAWAII BOARD OF MEDICAL EXAMINERS
PAIN MANAGEMENT GUIDELINES

Section I: Introduction

The Board of Medical Examiners ("Board") recognizes that principles of quality medical practice dictate that the people of the State of Hawaii have access to appropriate and effective pain relief. The Board affirms that controlled substances may be necessary to relieve pain, and the medical use of opioid analgesics is recognized to be part of legitimate medical practice.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. The Board believes that all physicians who treat patients directly should have sufficient knowledge about pain and its management to provide comfort for those in pain, or utilize consultations when possible to obtain necessary information to make treatment decisions for their patients. Accordingly, this policy has been developed to clarify the Board's position on pain management, particularly as related to the use of controlled substances.

The Board is obligated under the laws of the State of Hawaii to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances. The Board considers acceptable the ordering, prescribing, dispensing or administration of controlled substances, including opioid analgesics, for a legitimate medical purpose to be acceptable particularly in the case of terminal illness. The Board considers the use of controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain.

The Board will consider the inappropriate treatment of pain to be a departure from standards of practice and therefore investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate to the diagnosis.

Section II: Evaluation of Physician Practice

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on a case-by-case basis. Deviation from this policy may be appropriate when contemporaneous medical records document reasonable cause for deviation.

In determining whether the physician has acted appropriately, the Board will consider the clinical outcome, whether drugs used are appropriate for the type of pain, and whether there is improvement in patient functioning and/or quality of life as factors.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

Section III: Practice Guidelines for Chronic Pain Management

Evaluation of the Patient – A medical history and physical examination should be performed and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse or other compulsive behaviors.

Treatment Plan – The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. The treatment plan should be adjusted and documented according to the individual needs of each patient.

Informed Consent and Agreement for Treatment – The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian. The patient's pain medication should be managed by one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should have written treatment agreements outlining the patient's responsibilities during treatment and should obtain informed consent before prescriptions are provided.

The treatment agreements may specify many of the following items:

- Urine or blood samples will be provided by patients upon request for urine/serum drugs of abuse screening and/or determining medication levels by their physicians;
- The number and frequency of all prescription refills may be limited at their physicians' discretion;
- Therapy with controlled substances may be discontinued by physicians under certain situations (e.g. significant violation of treatment agreements by patients);
- Physician/patient relationships may be discontinued under certain situations (e.g. violation of treatment agreements by patients);
- Medication refills will be provided under specified rules, within mutually agreed upon time-frames (e.g. early refills may not be allowed, lost medications may not be replaced, refills may only occur during regular business hours, etc.);
- All therapies may be provided on a time-limited basis to determine potential effectiveness, and may be discontinued if judged ineffective or unacceptably toxic;
- Referral of patients to substance abuse treatment programs will occur when use of controlled substances is determined to be due to underlying addiction and not pain.

Periodic Review - The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives.

Use of consultation with pain management specialists, addiction medicine specialists, and other medical specialties is encouraged. Physicians should be willing to refer their patients as necessary for additional evaluations and therapies to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion.

[CONTINUED ON NEXT PAGE]

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

Medical Records – The physician should keep accurate, current and complete medical records. Elements considered for completeness may include, but are not limited to the following:

1. An initial medical history and physical examination;
3. Diagnostic imaging, therapeutic and laboratory results;
4. Ongoing evaluations and consultations;
5. Establishment of treatment objectives;
6. Discussion and documentation of risks, benefits and alternatives;
7. Results of treatment(s) provided (changes in pain intensity and character, interference with activities of daily living), and management of side effects;
8. Intended use of medications (information about date, name of medication, dosage, quantity prescribed with instructions);
9. Treatment instructions and agreements provided; and
10. Evidence of ongoing periodic review process with treatment modification if necessary.

Compliance With Controlled Substances Laws and Rules – To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state laws and rules.

Section IV: Definitions (as taken from the Federation of State Medical Boards)

For the purpose of these guidelines, the following terms are defined as follows:

Pain - An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Acute Pain – Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with an invasive procedure, trauma or disease. It is generally time-limited.

Chronic Pain – Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

(+) *CRITERION 7: Physical dependence or analgesic tolerance are not confused with "addiction"*

Addiction – Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Physical Dependence - Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Tolerance - Tolerance is a physiological state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Substance Abuse – Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  General Laws; Title 37. Food, Drugs, and Oil; Chapter 27. Uniform Controlled Substances

- MEDICAL PRACTICE ACT (*No provisions found*)
  General Laws; Title 54. Professions, Vocations and Businesses; Chapter 18. Physicians and Surgeons; Medical Practice Act

- PHARMACY PRACTICE ACT
  General Laws; Title 54. Professions, Vocations and Businesses; Chapter 17. Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  No policy found

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  IDAPA 22. Board of Medicine

- PHARMACY BOARD REGULATIONS
  IDAPA 27. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Idaho State Board of Medicine. *Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: August 26, 2005.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- REQUIREMENTS FOR BEHAVIOR MANAGEMENT
  IDAPA 16. Department of Health and Welfare; Title 03. Division of Welfare; Chapter 22. Residential Care or Assisted Living Facilities in Idaho

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Provisions that may *ENHANCE* pain management

Criteria	1	2	3	4	5	6	7	8
	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with "addiction"	Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Pharmacy Practice Act			●					
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[2]								
Medical Board[1]								
Pharmacy Board			●					
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Requirements for Behavior Management								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[2]								
Medical Board[1]								
Pharmacy Board			●					
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Requirements for Behavior Management[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Idaho Code § 37-2701

§ 37-2701. Definitions

As used in this act:

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(z) "Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of his professional practice or research in this state;

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(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Idaho Code § 54-1705

§ 54-1705. Definitions

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(24) "Practitioner" shall mean a physician, dentist, veterinarian, scientific investigator or other person (other than a pharmacist) licensed in this state and permitted by such license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research in this state.

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(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

ID BReg 432.

Definitions: A -- G.

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09. Drug Dependent Person. The term "Drug Dependent Person" means a person who is using a controlled substance (as defined in Section 37-2720, Idaho Code) and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis.

10. Drug Dependence. Drug dependence is defined as characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.

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IDAPA 27.01.01.433

433. DEFINITIONS - (H -- Z).

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02. Individual Practitioner. The term "individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the state in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Idaho State Board of Medicine
Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Idaho State Board of Medicine recognizes that principles of quality medical practice dictate that the people of the State of Idaho have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, under treatment, over treatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Idaho State Board of Medicine is obligated under the laws of the State of Idaho to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

[CONTINUED]

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines
The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements and
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions
For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

[CONTINUED ON NEXT PAGE]

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Requirements for Behavior Management

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (behavior management evaluation) for residential care or assisted living facilities to ensure that pain management is an essential part of patient care.

IDAPA 16.03.22.225

225. REQUIREMENTS FOR BEHAVIOR MANAGEMENT.

The facility must identify and evaluate behavioral symptoms that are distressing to the resident or infringe on other residents' rights. Effective Date: (3-30-06)

01. Evaluation for Behavior Management. The facility evaluation must include the following; Effective Date: (3-30-06)

a. Identification if the resident behavior is transitory or permanent; Effective Date: (3-30-06)

b. Review of the resident's previous behaviors and activities; Effective Date: (3-30-06)

c. Review of baseline data including intensity, duration and frequency of the resident behavior; Effective Date: (3-30-06)

d. Identification of recent changes in the resident's life, such as death in the family, change in resident's daily routine, or changes in the Resident's Negotiated Service Agreement; Effective Date: (3-30-06)

e. Identification of environmental causes that could contribute to the resident's behavior such as excessive heat, noise, overcrowding, hunger, staffing; Effective Date: (3-30-06)

f. Rule out possible medical causes such as pain, constipation, fever, infection, or medication side effects; and Effective Date: (3-30-06)

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

ILLINOIS

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Chapter 720. Criminal Offenses; Offenses Against the Public; Illinois Controlled Substances Act

- MEDICAL PRACTICE ACT (*No provisions found*)
  Chapter 225. Professions and Occupations; Health; Medical Practice Act of 1987

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Chapter 225. Professions and Occupations; Health; Osteopathic and Allopathic Healthcare Discrimination Act

- PHARMACY PRACTICE ACT (*No provisions found*)
  Chapter 225. Professions and Occupations; Health; Pharmacy Practice Act of 1987

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 77. Public Health; Chapter XV. Department of Professional Regulation; Part 3100. Illinois Controlled Substances Act

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 68. Professions and Occupations; Chapter VII. Department of Financial and Professional Regulation; Subchapter b. Professions and Occupations; Part 1285. Medical Practice Act of 1987

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 68. Professions and Occupations; Chapter VII. Department of Financial and Professional Regulation; Subchapter b. Professions and Occupations; Part 1330. Pharmacy Practice Act of 1987

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HOSPICE SERVICES

  Title 77. Public Health; Chapter I. Department of Public Health; Subchapter b. Hospitals and Ambulatory Care Facilities; Part 280. Hospice Programs; Subpart B. Hospice Services

- ELECTRONIC PRESCRIPTION MONITORING PROGRAM

  Title 77. Public Health; Chapter X. Department of Alcoholism and Substance Abuse; Subchapter e. Controlled Substances Activities; Part 2080. Electronic Prescription Monitoring Program

Note: Illinois Controlled Substances Regulations continue to reference the triplicate prescription program that was repealed in 2000; although not considered a barrier to practice, efforts should be made to remove from state law all references to this vestigial policy.

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Services								●
Electronic Prescription Monitoring Program[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act					●			
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Services[1]								
Electronic Prescription Monitoring Program					●			

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

720 ILCS 570/102

§ 720 ILCS 570/102. Definitions

Sec. 102. Definitions. As used in this Act, unless the context otherwise requires:

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(kk) "Practitioner" means a physician licensed to practice medicine in all its branches, dentist, optometrist, podiatrist, veterinarian, scientific investigator, pharmacist, physician assistant, advanced practice nurse, licensed practical nurse, registered nurse, hospital, laboratory, or pharmacy, or other person licensed, registered, or otherwise lawfully permitted by the United States or this State to distribute, dispense, conduct research with respect to, administer or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

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(+) *CRITERION 3:*
Opioids are part of professional practice

720 ILCS 570/312

§ 720 ILCS 570/312. Requirements for dispensing controlled substances

Sec. 312. Requirements for dispensing controlled substances. (a) A practitioner, in good faith, may dispense a Schedule II controlled substance, which is a narcotic drug listed in Section 206 of this Act [720 ILCS 570/206]; or which contains any quantity of amphetamine or methamphetamine, their salts, optical isomers or salts of optical isomers; phenmetrazine and its salts; pentazocine; or which is hereafter determined to be a "designated product," as defined in Section 102 of this Act [720 ILCS 570/102] and Schedule III, IV, or V controlled substances to any person upon a written prescription of any prescriber, dated and signed by the person prescribing on the day when issued and bearing the name and address of the patient for whom, or the owner of the animal for which the controlled substance is dispensed, and the full name, address and registry number under the laws of the United States relating to controlled substances of the prescriber, if he is required by those laws to be registered. If the prescription is for an animal it shall state the species of animal for which it is ordered. The practitioner filling the prescription shall write the date of filling and his own signature on the face of the written prescription. The written prescription shall be retained on file by the practitioner who filled it or pharmacy in which the prescription was filled for a period of 2 years, so as to be readily accessible for inspection or removal by any officer or employee engaged in the enforcement of this Act. Whenever the practitioner's or pharmacy's copy of any prescription is removed by an officer or employee engaged in the enforcement of this Act, for the purpose of investigation or as evidence, such officer or employee shall give to the practitioner or pharmacy a receipt in lieu thereof. A prescription form for a Schedule II controlled substance shall not be filled more than 7 days after the date of issuance. A written prescription for Schedule III, IV or V controlled substances shall not be filled or refilled more than 6 months after the date thereof or refilled more than 5 times unless renewed, in writing, by the prescriber.

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(-) *CRITERION 13:*
Length of prescription validity is restricted

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

77 Ill. Adm. Code 3100.400

§ 3100.400 Requirement of Prescription.

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b) An individual practitioner may administer or dispense directly a controlled substance listen in Schedule II in the course of his professional practice subject to the Act and this Part.

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(+) *CRITERION 3: Opioids are part of professional practice*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospice Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

77 Ill. Adm. Code 280.2070

§ 280.2070 Medical Director and Physician Services

a) The hospice program shall have a medical director who shall be a doctor of medicine or osteopathy and licensed to practice medicine in all of its branches. (Section 8(d) of the Act) In his/her absence, the medical director or governing

b) The medical director shall have overall responsibility for medical direction of the patient care component of the hospice program and shall consult and cooperate with the patient's attending physician. (Section 8(d) of the Act)

c) Duties of the medical director shall include but not be limited to:

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9) Approving written guidelines for symptom control, i.e., pain, nausea, vomiting, or other symptoms.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written guidelines) for hospices to ensure that pain management is an essential part of patient care.

REGULATIONS

Electronic Prescription Monitoring Program

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

77 Ill. Adm. Code 2080.70

§ 2080.70 Schedule II Drug Prescription Requirements

a) A dispenser may fill a prescription for a Schedule II drug upon receipt of a written, facsimile or verbal order of a physician unless otherwise specifically exempted or allowed by federal or State law.

b) A prescription for a Schedule II drug shall:

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9) Not be filled more than seven days after the date of issue;

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(-) *CRITERION 13:*
Length of prescription validity is restricted

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

IN

INDIANA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 35. Criminal Law and Procedure; Article 48. Controlled Substances

- MEDICAL PRACTICE ACT
  Title 25. Professions and Occupations; Article 22.5. Physicians

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 25. Professions and Occupations; Article 26. Pharmacists and Pharmacies or Drugstores

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*)
  Title 858. Controlled Substances Advisory Committee

- MEDICAL BOARD REGULATIONS
  Title 844. Medical Licensing Board of Indiana;

- PHARMACY BOARD REGULATIONS
  Title 856. Indiana Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HOMICIDE
  Title 35. Criminal Law and Procedure; Article 42. Offenses Against the Person; Chapter 1. Homicide

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					●
Medical Practice Act		●						
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Homicide								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management								
Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board			●					
Pharmacy Board								●
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Homicide[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

INDIANA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

Burns Ind. Code Ann. § 35-48-1-24

§ 35-48-1-24. Practitioner

"Practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other institution or individual licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in Indiana.

Burns Ind. Code Ann. § 35-48-7-8

§ 35-48-7-8.1 Advisory committee to provide for controlled substance prescription monitoring program – Components of program.

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(4) The advisory committee may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the advisory committee may not apply such a requirement to prescriptions filled at a pharmacy with a Type II permit (as described in *IC 25-26-13-17*) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The committee may not require multiple copy prescription forms and serially numbered prescription forms for any prescriptions written. The advisory committee may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be jointly approved by the committee and by the Indiana board of pharmacy established by *IC 25-26-13-3*.

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Burns Ind. Code Ann. § 35-48-7-11.1

35-48-7-11.1. Information received by INSPECT program confidential -- Release of confidential information -- Procedures for release of confidential information -- Use of information as evidence -- Civil immunity.

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(h) The advisory committee may release to:

(1) a member of the board, the advisory committee, or another governing body that licenses practitioners;

(2) an investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general; or

(3) a law enforcement officer who is:

(A) authorized by the state police department to receive the type of information released; and

(B) approved by the advisory committee to receive the type of information released;

confidential information generated from computer records that identifies practitioners who are prescribing or dispensing large quantities of a controlled substance.

(i) The information described in subsection (h) may not be released until it has been reviewed by:

(1) a member of the advisory committee who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data; or

(2) the advisory committee's designee;

and until that member or the designee has certified that further investigation is warranted. However, failure to comply with this subsection does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (j).

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes characteristics of prescription monitoring programs that are believed to impede the appropriate medical use of Schedule II controlled substances.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (review by advisory committee member with the same professional license) to determine from prescription monitoring program information whether further investigation for a particular case of improper prescribing is warranted.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Burns Ind. Code Ann. § 25-22.5-1-1.1

§ 25-22.5-1-1.1. Definitions

As used in this article:

(a) “Practice of medicine or osteopathic medicine” means any one (1) or a combination of the following:

(1) Holding oneself out to the public as being engaged in:

(A) the diagnosis, treatment, correction, or prevention of any disease, ailment, defect, injury, infirmity, deformity, pain, or other condition of human beings;

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(+) *CRITERION 2:*
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

INDIANA

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

856 IAC 2-1-1

856 IAC 2-1-1 Definitions

Sec. 1. Definitions. As used herein, the following terms shall have the meanings specified:

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(h) The term "individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted by the State of Indiana or the United States, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

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(+) *CRITERION 3:*
Opioids are part of professional practice

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

844 IAC 5-1-1

844 IAC 5-1-1 Definitions

Sec. 1. For purposes of this article and IC 25-1-9, the following definitions apply:

(1) "Addict" means a person who is physiologically and/or psychologically dependent upon a drug that is classified as a narcotic, controlled substance, or dangerous drug.

(2) "Habitue" means a person who: (A) is physiologically and/or psychologically dependent upon any narcotic, drug classified as a narcotic, dangerous drug, or controlled substance under Indiana law; or (B) consumes, on a regular basis and without any medically justifiable purpose, a narcotic drug classified as a narcotic, dangerous drug, or controlled substance under Indiana law, whether or not such person has developed a physiological or psychological dependence upon such substance.

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(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

856 IAC 2-6-3

856 IAC 2-6-3 Purpose of prescription; prohibitions

Sec. 3. Purpose of issue of prescription. (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose in a reasonable quantity by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription, within the meaning and intent of IC 1971, 35-24.1-3-8 [Repealed by Acts 1976, P.L. 148, SECTION 24; Acts 1977, P.L. 26, SECTION 25. See IC 35-48.] as amended, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT:
"Reasonable" implies there is a known standard, but the standard is not specified.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Homicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Burns Ind. Code Ann. § 35-42-1-2.5

§ 35-42-1-2.5. Assisting suicide

(a) This section does not apply to the following:

(1) A licensed health care provider who administers, prescribes, or dispenses medications or procedures to relieve a person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, unless such medications or procedures are intended to cause death.

(2) The withholding or withdrawing of medical treatment or life-prolonging procedures by a licensed health care provider, including pursuant to IC 16-36-4 (living wills and life-prolonging procedures), IC 16-36-1 (health care consent), or IC 30-5 (power of attorney).

(b) A person who has knowledge that another person intends to commit or attempt to commit suicide and who intentionally does either of the following commits assisting suicide, a Class C felony:

(1) Provides the physical means by which the other person attempts or commits suicide.

(2) Participates in a physical act by which the other person attempts or commits suicide.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title IV. Public Health; Subtitle 1. Alcoholic Beverages and Controlled Substances; Chapter 124. Controlled Substances

- MEDICAL PRACTICE ACT *(No provisions found)*
  Title IV. Public Health; Subtitle 3. Health-Related Professions; Chapter 148. Medicine and Surgery

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Title IV. Public Health; Subtitle 3. Health-Related Professions; Chapter 150A. Osteopathic Medicine and Surgery

- PHARMACY PRACTICE ACT
  Title IV. Public Health; Subtitle 3. Health-Related Professions; Chapter 155A. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Pharmacy Examiners Board; Chapter 10. Controlled Substances

- MEDICAL BOARD REGULATIONS (Governs Osteopathic *Board*)
  Medical Examiners Board [653]

- PHARMACY BOARD REGULATIONS (No provisions found)
  Pharmacy Examiners Board [657]

OTHER GOVERNMENTAL POLICIES

- PHARMACY BOARD POLICY STATEMENT
  Iowa Pharmacy Examiners Board. *The Treatment of Pain*. Adopted: February 12, 2002.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- CHEMICAL SUBSTANCE ABUSE
  Title IV. Public Health; Subtitle 1. Alcoholic Beverages and Controlled Substances; Chapter 125. Chemical Substance Abuse

- ASSISTING SUICIDE
  Title XVI. Criminal Law and Procedure; Subtitle 1. Crime Control and Criminal Acts; Chapter 707A. Assisting Suicide

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					●
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act			●					
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board		●	●	●				●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Pharmacy Board Policy Statement			●	●	●			●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Chemical Substance Abuse								●
Assisting Suicide								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Pharmacy Board Policy Statement							•	
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Chemical Substance Abuse[1]								
Assisting Suicide[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

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STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

Iowa Code § 124.101

124.101 Definitions.

As used in this chapter:

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25. *"Practitioner"* means either:

a. A physician, dentist, podiatric physician, veterinarian, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

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Iowa Code § 124.551

124.551 Information program for drug prescribing and dispensing.

Contingent upon the receipt of funds pursuant to section 124.557 sufficient to carry out the purposes of this division, the board, in conjunction with the advisory council created in section 124.555, shall establish and maintain an information program for drug prescribing and dispensing. The program shall collect from pharmacies dispensing information for controlled substances identified pursuant to section 124.554, subsection 1, paragraph *"g"*. The information collected shall be used by prescribing practitioners and pharmacists on a need-to-know basis for purposes of improving patient health care by facilitating early identification of patients who may be at risk for addiction, or who may be using, abusing, or diverting drugs for unlawful or otherwise unauthorized purposes at risk to themselves and others, or who may be appropriately using controlled substances lawfully prescribed for them but unknown to the practitioner. For purposes of this division, *"prescribing practitioner"* means a practitioner who has prescribed or is contemplating the authorization of a prescription for the patient about whom information is requested, and *"pharmacist"* means a practicing pharmacist who is actively engaged in and responsible for the pharmaceutical care of the patient about whom information is requested. The board shall collect, store, and disseminate program information consistent with security criteria established by rule, including use of appropriate encryption or other industry-recognized security technology. The board shall seek any federal waiver necessary to implement the provisions of the program.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that prescription monitoring programs may identify patients who are appropriately using controlled substances that are lawfully prescribed, but are obtained from more than one practitioner; such information could be used to address inadequate treatment and improve patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

Iowa Code § 155A.3

155A.3 Definitions.

As used in this chapter, unless the context otherwise requires:

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33. *"Practitioner"* means a physician, dentist, podiatric physician, veterinarian, or other person licensed or registered to distribute or dispense a prescription drug or device in the course of professional practice in this state or a person licensed by another state in a health field in which, under Iowa law, licensees in this state may legally prescribe drugs.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

653 IAC 1.1(17A,147)

653-1.1(17A,147) Definitions.

The following definitions shall be applicable to the rules of the board of medicine:

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"The practice of medicine and surgery" shall mean holding one's self out as being able to diagnose, treat, operate or prescribe for any human disease, pain, injury, deformity or physical or mental condition and who shall either offer or undertake, by any means or methods, to diagnose, treat, operate or prescribe for any human disease, pain, injury, deformity or physical or mental condition. This rule shall not apply to licensed podiatrists, chiropractors, physical therapists, nurses, dentists, optometrists, acupuncturists, pharmacists and other licensed health professionals who are exclusively engaged in the practice of their respective professions.

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653—13.2(148,150,150A,272C) Standards of practice—prescribing or administering controlled substances for the treatment of patients with chronic, nonmalignant pain.

This rule establishes standards of practice for the management of chronic, nonmalignant pain. The purpose of the rule is to assist physicians who prescribe and administer drugs to provide relief and eliminate suffering in patients with chronic, nonmalignant pain as defined in this rule.

13.2(1) *Definitions.* As used in this rule:
"Agency for Healthcare Research and Quality" or *"AHRQ"* means the agency within the U.S. Department of Health and Human Services which is responsible for establishing Clinical Practice Guidelines on various aspects of medical practice.

"American Academy of Pain Medicine" or *"AAPM"* means the American Medical Association-recognized specialty society of physicians who practice pain medicine in the United States. The mission of the AAPM is to enhance pain medicine practice by promoting a climate conducive to the effective and efficient practice of pain medicine.

"American Pain Society" or *"APS"* means the national chapter of the International Association for the Study of Pain, an organization composed of physicians, nurses, psychologists, scientists and other professionals who have an interest in the study and treatment of pain. The mission of the APS is to serve people in pain by advancing research, education, treatment and professional practice.

"Chronic, nonmalignant pain (i.e., not caused by cancer)" means persistent or episodic pain of a duration or intensity that adversely affects the functioning or well-being of a patient when (1) no relief or cure for the cause of pain is possible; (2) no relief or cure for the cause of pain has been found; or (3) relief or cure for the cause of pain through other medical procedures would adversely affect the well-being of the patient.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) CRITERION 4:
Encourages pain management

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) ***CRITERION 3:*** ***Opioids are part of professional practice***

(CONTINUED)

13.2(2) *General provisions.* Various controlled drugs, particularly opioid analgesics, can be safely and effectively utilized to control pain in certain patients. However, inappropriate prescribing of controlled substances can lead to, or accelerate, drug abuse and diversion. Therefore, the medical management of pain shall be based on a thorough knowledge of pain assessment, pain treatment, and concern for the patient.

a. Treatment of acute pain and cancer pain. Physicians may refer to the Clinical Practice Guidelines published by the AHRQ for counsel on the proper treatment of acute pain and chronic pain associated with cancer. The AHRQ Clinical Practice Guidelines provide a sound, compassionate, and flexible approach to the management of pain in these patients.

b. Treatment of chronic, nonmalignant pain. The basic premise underlying this rule is that various drugs, particularly opioid analgesics, may be useful for treating patients with chronic, nonmalignant pain in a safe, effective, and efficient manner when other efforts, including those by other practitioners or the patient, have failed to remove or effectively treat the pain. The board strongly recommends that physicians who have reservations about the use of drugs in the treatment of chronic, nonmalignant pain consult: Definitions Related to the Use of Opioids for the Treatment of Pain, a consensus document from the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the American Society of Addiction Medicine (ASAM) (2001). Copies of the document are available from the AAPM (http://www.painmed.org), the APS (http://www.ampainsoc.org), the ASAM (http://www.asam.org), and the office of the board at 400 S.W. 8th Street, Suite C, Des Moines, Iowa 50309-4686.

13.2(3) *Effective chronic, nonmalignant pain management.* To ensure that pain is properly and promptly assessed and treated, a physician who prescribes or administers controlled substances to a patient for the treatment of chronic, nonmalignant pain shall exercise sound clinical judgment by establishing accordance with the following:

a. Patient evaluation. A patient evaluation that includes a physical examination and a comprehensive medical history shall be conducted prior to the initiation of treatment. The evaluation shall also include an assessment of the pain, physical and psychological function, diagnostic studies, previous interventions, including medication history, substance abuse history and any underlying or coexisting conditions. Consultation/referral to a physician with expertise in pain medicine, addiction medicine or substance abuse counseling or a physician who specializes in the treatment of the area, system, or organ perceived to be the source of the pain may be warranted depending upon the expertise of the physician and the complexity of the presenting patient. Interdisciplinary evaluation is strongly encouraged.

b. Treatment plan. The physician shall establish a comprehensive treatment plan that tailors drug therapy to the individual needs of the patient. To ensure proper evaluation of the success of the treatment, the plan shall clearly state the objectives of the treatment, for example, pain relief, or improved physical or psychosocial functioning. The treatment plan shall also indicate if any further diagnostic evaluations or treatments are planned and their purposes. The treatment plan shall also identify any other treatment modalities and rehabilitation programs utilized.

c. Informed consent. The physician shall document discussion of the risks and benefits of controlled substances with the patient or person representing the patient.

(CONTINUED ON NEXT PAGE)

(+) ***CRITERION 8:*** ***Other provisions that may enhance pain management***

CATEGORY A: ***Issues related to healthcare professionals***

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

d. Periodic review. The physician shall periodically review the course of drug treatment of the patient and the etiology of the pain. Modification or continuation of drug therapy by the physician shall be dependent upon evaluation of the patient's progress toward the objectives established in the treatment plan. The physician shall consider the appropriateness of continuing drug therapy and the use of other treatment modalities if periodic reviews indicate the objectives of the treatment plan are not being met or there is evidence of diversion or a pattern of substance abuse.

e. Consultation/referral. The physician shall consider consultation with, or referral to, a physician with expertise in pain medicine, addiction medicine or substance abuse counseling, if the objectives of the treatment plan are not being met or there is evidence of diversion or a pattern of substance abuse.

f. Documentation. The physician shall keep accurate, timely, and complete records that detail compliance with this subrule, including patient evaluation, diagnostic studies, treatment modalities, treatment plan, informed consent, periodic review, consultation, and any other relevant information about the patient's condition and treatment.

g. Physician-patient agreements. Physicians treating patients at risk for substance abuse shall consider establishing physician-patient agreements that specify the rules for medication use and the consequences for misuse. In preparing agreements, a physician shall evaluate the case of each patient on its own merits, taking into account the nature of the risks to the patient and the potential benefits of treatment.

h. Termination of care. The physician shall consider termination of patient care if there is evidence of diversion or a repeated pattern of substance abuse.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Pharmacy Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

THE TREATMENT OF PAIN

The mission of the Iowa Board of Pharmacy Examiners is to promote, preserve and protect the public health, safety and welfare by fostering the provision of quality pharmaceutical care to all Iowans. As part of that endeavor, the Board strives to ensure that all Iowans have access to pain relief medication. Appropriate and effective use of pain medication can improve a patient's quality of life and reduce costs associated with inadequately treated pain, whether due to cancer or non-cancer origins. Inadequate pain control often results from a lack of knowledge and/or understanding of proper pain management by health care professionals and patients. All pharmacists should increase their knowledge of current medical standards for the treatment of pain, develop effective strategies for delivering pharmaceutical care to patients suffering from pain, and actively participate as a member of the health care team by providing pharmaceutical expertise to the patient, physician, nurse, and hospice provider or other caregiver.

The Board recognizes that the use of controlled substances, including opioid analgesics, is often essential for adequate pain control. The sustained use of these drugs may result in physical and psychological dependence; thus care must be taken to balance these risks against the desired outcome of effective pain control. Health care professionals must remain alert to the fact that these drugs are subject to abuse and some patients will seek them for illegitimate uses.

Controlled substances shall only be dispensed for legitimate medical purposes. Dispensing controlled drugs to a patient without a legitimate medical purpose violates state and federal laws. Dispensing must be based on a valid prescription issued within currently accepted medical standards for the treatment of pain. Pharmacists who dispense such medications pursuant to a legitimate prescription and in conformance with the standard of care need not fear action by the Board. By participating as a member of the health care team, pharmacists can ensure quality pharmaceutical care for patients suffering from pain and can reduce the potential for drug diversion and abuse. Proper documentation of the patient's medical condition and clinical response to treatment provides a strong foundation for establishing optimal patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(-) *CRITERION 15:*
Other provisions that may impede pain management

COMMENT: To what extent does physical dependence constitute a risk?

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Chemical Substance Abuse

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Iowa Code § 125.2

125.2 Definitions.

For purposes of this chapter, unless the context clearly indicates otherwise:

1. *"Chemical dependency"* means an addiction or dependency, either physical or psychological, on a chemical substance. Persons who take medically prescribed drugs shall not be considered chemically dependent if the drug is medically prescribed and the intake is proportionate to the medical need.

. . .

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: This definition, used in addiction treatment, would ensure that pain patients would not be labeled as chemically dependent; however, the definition seems to confuse physical dependence with addiction for general purposes.

STATUTES

Assisting Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Iowa Code § 707A.3

707A.3 Acts or omissions not considered assisting suicide

1. A licensed health care professional who administers, prescribes, or dispenses medications or who performs or prescribes procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, does not violate section 707A.2 unless the medications or procedures are intentionally or knowingly administered, prescribed, or dispensed with the primary intention of causing death.

. . .

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

KS

KANSAS

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT *(No provisions found)*
  Chapter 65. Public Health; Article 41. Controlled Substances; Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Chapter 65. Public Health; Article 28. Healing Arts; Kansas Healing Arts Act

- PHARMACY PRACTICE ACT *(No provisions found)*
  Chapter 65. Public Health; Article 16. Regulation of Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Agency 68. Kansas State Board of Pharmacy; Article 20. Controlled Substances

- MEDICAL BOARD REGULATIONS *(No provisions found)*
  Agency 100. Kansas State Board of Healing Arts

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Agency 68. Kansas State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Kansas State Board of Healing Arts. *Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted: October 17, 1998.

- JOINT BOARD POLICY STATEMENT
  Kansas State Boards of Healing Arts, Nursing, and Pharmacy. J*oint Policy Statement by the Boards of Healing Arts, Nursing, and Pharmacy on the Use of Controlled Substances for the Treatment of Pain*. Adopted: July 17, 2002.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- PREVENTION OF ASSISTED SUICIDE
  Chapter 60. Procedure, Civil; Article 44. Prevention of Assisted Suicide

- PAIN PATIENT'S QUALITY OF CARE
  Chapter 65. Public Health; Article 49. Health Care Providers

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act								●
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
Joint Board Policy Statement			●	●	●		●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Prevention of Assisted Suicide								●
Pain Patient's Quality of Care			●					●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
Joint Board Policy Statement[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Prevention of Assisted Suicide[1]								
Pain Patient's Quality of Care[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (board guidelines) to provide practitioners information/education about pain management.

K.S.A. § 65-2838

65-2838. Disciplinary action against licensee; procedure; stipulations; temporary suspension or limitation; emergency proceedings; guidelines for use of controlled substances for treatment of pain; written advisory opinions.

(a) The board shall have jurisdiction of proceedings to take disciplinary action authorized by *K.S.A. 65-2836* and amendments thereto against any licensee practicing under this act. Any such action shall be taken in accordance with the provisions of the Kansas administrative procedure act.

(b) Either before or after formal charges have been filed, the board and the licensee may enter into a stipulation which shall be binding upon the board and the licensee entering into such stipulation, and the board may enter its findings of fact and enforcement order based upon such stipulation without the necessity of filing any formal charges or holding hearings in the case. An enforcement order based upon a stipulation may order any disciplinary action authorized by *K.S.A. 65-2836* and amendments thereto against the licensee entering into such stipulation.

(c) The board may temporarily suspend or temporarily limit the license of any licensee in accordance with the emergency adjudicative proceedings under the Kansas administrative procedure act if the board determines that there is cause to believe that grounds exist under *K.S.A. 65-2836* and amendments thereto for disciplinary action authorized by *K.S.A. 65-2836* and amendments thereto against the licensee and that the licensee's continuation in practice would constitute an imminent danger to the public health and safety.

(d) The board shall adopt guidelines for the use of controlled substances for the treatment of pain.

(e) Upon request of another regulatory or enforcement agency, or a licensee, the board may render a written advisory opinion indicating whether the licensee has prescribed, dispensed, administered or distributed controlled substances in accordance with the treatment of pain guidelines adopted by the board.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

KANSAS

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES
FOR THE TREATMENT OF PAIN

Section 1: Preamble

The Kansas State Board of Healing Arts recognizes that principles of quality medical practice dictate that the people of the State of Kansas have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The Kansas State Board of Healing Arts is obligated under the laws of the State of Kansas to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

Physicians should not fear disciplinary action from the Board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with these guidelines. If such prescribing meets these criteria, the Board will support physicians whose use of controlled substances has been questioned by another regulatory or enforcement agency.

Allegations of improper prescribing of controlled substances for pain will be evaluated on a case-by-case basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs - including any improvement in functioning - and recognizing that some types of pain cannot be completely relieved.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

[CONTINUED]

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient

The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (i.e., violation of agreement).

4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and / or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

5. Consultation

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records

The physician should comply with and meet the requirements of K.A.R. 100-24-1 in the maintenance of an adequate record for each patient.

7. Compliance With Controlled Substances Laws and Regulations

To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain

Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction

Addiction is a neuro-behavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Analgesic Tolerance

Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain

A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain

An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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Physical Dependence

Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Pseudo-Addiction

Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse

Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance

Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

KANSAS

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

JOINT POLICY STATEMENT BY THE BOARDS OF HEALING ARTS, NURSING, AND PHARMACY ON THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Section 1: Preamble

The Kansas Legislature created the Board of Healing Arts, the Board of Nursing, and the Board of Pharmacy to protect the public health, safety and welfare. Protection of the public necessitates reasonable regulation of health care providers who order, administer, or dispense drugs. The boards adopt this statement to help assure health care providers and patients and their families that it is the policy of this state to encourage competent comprehensive care for the treatment of pain. Guidelines by individual boards are appropriate to address issues related to particular professions.

The appropriate application of current knowledge and treatment modalities improves the quality of life for those patients who suffer from pain, and reduces the morbidity and costs associated with pain that is inappropriately treated. All health care providers who treat patients in pain, whether acute or chronic, and whether as a result of terminal illness or non-life-threatening injury or disease, should become knowledgeable about effective methods of pain treatment. The management of pain should include the use of both pharmacologic and non-pharmacologic modalities.

Inappropriate treatment of pain is a serious problem in the United States. Inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and ineffective treatment. All persons who are experiencing pain should expect the appropriate assessment and management of pain while retaining the right to refuse treatment. A person's report of pain is the optimal standard upon which all pain management interventions are based. The goal of pain management is to reduce the individual's pain to the lowest level possible, while simultaneously increasing the individual's level of functioning to the greatest extent possible. The exact nature of these goals is determined jointly by the patient and the health care provider.

Prescribing, administering or dispensing controlled substances, including opioid analgesics, to treat pain is considered a legitimate medical purpose if based upon sound clinical grounds. Health care providers authorized by law to prescribe, administer or dispense drugs, including controlled substances, should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

A board is under a duty to make an inquiry when it receives information contending that a health care provider treated pain inappropriately. Proper investigation is necessary in order to obtain relevant information. A health care provider should not construe any request for information as a presumption of misconduct. Prior to the filing of any allegations, the results of the investigation will be evaluated by the health care provider's peers who are familiar with this policy statement. Health care providers who competently treat pain should not fear disciplinary action from their licensing board.

The following guidelines are not intended to define complete or best practice, but rather to communicate what the boards consider to be within the boundaries of professional practice. This policy statement is not intended to interfere with any healthcare provider's professional duty to exercise that degree of learning and skill ordinarily possessed by competent members of the healthcare provider's profession.

Section II: Principles

The boards approve the following principles when evaluating the use of controlled substances for pain control

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes the patient's right to request or reject different types of treatments.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

1. Assessment of the Patient
Pain should be assessed and reassessed as clinically indicated. Interdisciplinary communications regarding a patient's report of pain should include adoption of a standardized scale for assessing pain.

2. Treatment Plan
The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the drug therapy plan should be adjusted to the individual medical needs of each patient. The nurse's skill is best utilized when an order for drug administration uses dosage and frequency parameters that allow the nurse to adjust (titrate) medication dosage. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. If, in a healthcare provider's sound professional judgement, pain should not be treated as requested by the patient, the healthcare provider should inform the patient of the basis for the treatment decisions and document the substance of this communication.

3. Informed Consent
The physician retains the ultimate responsibility for obtaining informed consent to treatment from the patient. All health care providers share the role of effectively communicating with the patient so that the patient is apprised of the risks and benefits of using controlled substances to treat pain.

4. Agreement for Treatment of High-Risk Patients
If the patient is determined to be at high risk for medication abuse or to have a history of substance abuse, the health care provider should consider requiring a written agreement by the patient outlining patient responsibilities, including:
- Submitting to screening of urine/serum medication levels when requested;
- Limiting prescription refills only to a specified number and frequency;
- Requesting or receiving prescription orders from only one health care provider;
- Using only one pharmacy for filling prescriptions; and
- Acknowledging reasons for which the drug therapy may be discontinued (i.e., violation of agreement).

5. Periodic Review
At reasonable intervals based on the individual circumstances of the patient, the course of treatment and any new information about the etiology of the pain should be evaluated. Communication among health care providers is essential to review of the medical plan of care. The health care providers involved with the management of pain should evaluate progress toward meeting treatment objectives in light of improvement in patient's pain intensity and improved physical or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved despite medication adjustments, the health care provider's should reevaluate the appropriateness of continued treatment.

6. Consultation
The health care provider should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement poses a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

7. Medical Records
The medical record should document the nature and intensity of the pain and contain pertinent information concerning the patient's health history, including treatment for pain or other underlying or coexisting conditions. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

8. Compliance With Controlled Substances Laws and Regulations
To prescribe, dispense or administer controlled substances within this state, the health care provider must be licensed according to the laws of this state and comply with applicable federal and state laws.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies

Addiction is a neuro-behavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to as "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction. Addiction must be distinguished from pseudoaddiciton, which is a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic pain is a pain state which is persistent beyond the usual course of an acute disease or a reasonable time for an injury to heal, or that is associated with a chronic pathologic process that causes continuous pain or pain that recurs at intervals for months or years.

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

KANSAS

STATUTES

Prevention of Assisted Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

K.S.A. § 60-4403

60-4403. Standard of conduct of licensed health care professional related to assisting suicide; family member conduct; spiritual treatment.

(a) A licensed health care professional who administers, prescribes or dispenses medications or procedures to relieve another person's pain or discomfort does not violate *K.S.A. 21-3406* and amendments thereto unless the medications or procedures are knowingly administered, prescribed or dispensed with the intent to cause death. A mid-level practitioner as defined in subsection (ii) of *K.S.A. 65-1626* and amendments thereto who prescribes medications or procedures to relieve another person's pain or discomfort does not violate *K.S.A. 21-3406* and amendments thereto unless the medications or procedures are knowingly prescribed with the intent to cause death.

(b) A licensed health care professional, family member or other legally authorized person who participates in the act of, or the decision making process which results in the withholding or withdrawal of a life-sustaining procedure does not violate *K.S.A. 21-3406* and amendments thereto.

(c) Providing spiritual treatment through prayer alone, in lieu of medical treatment, does not violate *K.S.A. 21-3406* and amendments thereto.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

STATUTES

Pain Patient's Quality of Care

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

K.S.A. § 65-4976

65-4976. Legislative findings on pain treatment.

The legislature finds and declares that pain is a significant health problem, and that the diagnosis and treatment of pain is complex, and can involve several therapeutic modalities. The treatment of pain may require the use of controlled substances in appropriate circumstances. In order to promote the public health, safety and welfare, the state has a duty to restrict the inappropriate use of controlled substances while supporting a physician's or other health care provider's ability to provide appropriate pain treatment consistent with patient needs and sound clinical judgment.

65-4977. Persons suffering from pain; use of controlled substances for pain treatment.

(a) A person suffering from pain:

(1) Should be an active participant in decisions about the assessment, diagnosis and treatment of their pain.

(2) May accept or reject the use of any or all diagnostic and therapeutic modalities which may be recommended to treat such person's pain.

(3) Should accurately, completely, and honestly report all symptoms and concerns to physicians and other health care professionals conducting assessment and treatment of such person's pain.

(b) Nothing in this act shall be construed to prevent, restrict or limit a physician or other person authorized to prescribe drugs from prescribing, dispensing, administering, or distributing a controlled substance to a patient for the treatment of pain, when it is for a valid medical purpose and based on appropriate clinical indications.

(c) Nothing in this act shall be construed to require a physician or other person authorized to prescribe drugs to prescribe, dispense, administer, or distribute a controlled substance to a patient for the treatment of pain if in the judgment of the prescriber the use of a controlled substance is not clinically indicated or the most appropriate therapeutic modality.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes the patient's right to request or reject different types of treatments.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

KY

KENTUCKY

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title XVIII. Public Health; Chapter 218A. Controlled Substances

- MEDICAL PRACTICE ACT
  Title XXVI. Occupations and Professions; Chapter 311. Physicians, Osteopaths, Podiatrists and Related Medical Practitioners

- PHARMACY PRACTICE ACT *(No provisions found)*
  Title XXVI. Occupations and Professions; Chapter 315. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS *(No provisions found)*
  Title 902. Cabinet for Health and Family Services Department for Public Health; Chapter 55. Controlled Substances

- MEDICAL BOARD REGULATIONS *(No provisions found)*
  Title 201. General Government Cabinet; Chapter 9. Board of Medical Licensure

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 201. General Government Cabinet; Chapter 2. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Kentucky Board of Medical Licensure. *Guidelines for the Use of Controlled Substances in Pain Treatment*. Adopted: March 22, 2001; Amended: September 18, 2003.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- SUICIDE ASSISTANCE
  Title XVII. Public Health; Chapter 216. Health Facilities and Services; Suicide Assistance

KY

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Suicide Assistance								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act								●
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline	●							
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Suicide Assistance[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

KENTUCKY

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

KRS § 218A.010

218A.010. Definitions for chapter.

As used in this chapter:

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(26) "Practitioner" means a physician, dentist, podiatrist, veterinarian, scientific investigator, optometrist as authorized in *KRS 320.240*, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state. "Practitioner" also includes a physician, dentist, podiatrist, or veterinarian who is a resident of and actively practicing in a state other than Kentucky and who is licensed and has prescriptive authority for controlled substances under the professional licensing laws of another state, unless the person's Kentucky license has been revoked, suspended, restricted, or probated, in which case the terms of the Kentucky license shall prevail.

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(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

KRS § 311.597

§ 311.597. Acts declared to constitute dishonorable, unethical, or unprofessional conduct

As used in KRS 311.595(9), "dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public or any member thereof" shall include, but not be limited to, the following acts by a licensee:

(1) Prescribes or dispenses any medication:

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(d) In such amounts that the licensee knows or has reason to know, under the attendant circumstances, that said amounts so prescribed or dispensed are excessive under accepted and prevailing medical practice standards.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: "Excessive" implies there is a limit, but the limit is not specified.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

KENTUCKY

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES IN PAIN TREATMENT

Introduction

The Kentucky Board of Medical Licensure (KBML) recognizes that principles of quality medical practice dictate that the people of Kentucky have access to appropriate and effective pain relief. The appropriate application of state-of-the-art treatment modalities can serve not only to improve the quality of life for those patients who suffer from pain but also can reduce the morbidity and costs associated with inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic. Pain management is particularly important for patients who experience pain as a result of terminal illness and can be difficult for patients with chronic nonterminal pain. It is imperative that physicians become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result either from physicians' lack of knowledge about pain management or their misunderstanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of the pain patient. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, especially as related to the use of controlled substances for nonterminal/nonmalignant chronic pain, in order to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances (including opioid analgesics, benzodiazepines, and stimulants) may be essential in the treatment of acute pain and chronic pain, whether due to cancer or noncancer origins. Physicians are referred to the US Agency for Health Care Policy and Research Clinical Practice Guidelines[1] for a sound approach to the management of acute and chronic, malignant and non-malignant pain. The medical management of pain should be based on current knowledge and research and includes the use of both pharmacological and non-pharmacological modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that *tolerance* and *physical dependence* are normal consequences of sustained use of opioid analgesics and are not synonymous with *addiction. Addiction* refers to both dependence on the use of substances for the drug's psychic effects and compulsive use of the drug despite consequences.

The KBML is obligated under the laws of the state of Kentucky to protect the public health and safety. The Board recognizes that the inappropriate prescribing of controlled substances may lead to drug diversion and abuse by individuals who seek the drugs for other than legitimate medical use. Physicians must be diligent in preventing the diversion of drugs for illegitimate purposes. The Board believes the adoption of these guidelines will protect legitimate medical uses of controlled substances, while helping to prevent drug diversion and eliminating inappropriate prescribing practices.

Physicians should not fear disciplinary action from the Board for prescribing controlled substances for a legitimate medical purpose and in the usual course of professional practice. The Board will consider the prescribing of controlled substances for pain a legitimate medical purpose if such prescribing is (1) based on accepted scientific knowledge of pain treatment and (2) if based on sound clinical grounds. All such prescribing must be grounded in clear documentation of unrelieved pain and in compliance with applicable state or federal law.

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(+) CRITERION 2:
Pain management is part of medical practice

(+) CRITERION 4:
Encourages Pain Management

(+) CRITERION 7:
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

(+) CRITERION 5:
Addresses fear of regulatory scrutiny

(+) CRITERION 3:
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

KENTUCKY

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Each case of prescribing for pain will be evaluated on an individual basis if and when brought to the Board's attention. The Board does not take disciplinary action against a physician who fails to adhere strictly to the provisions of these guidelines if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account: (1) whether or not the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis; (2) the patient's individual needs–including improvement in functioning; and (3) a recognition that some types of pain cannot be completely relieved.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than only on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within acceptable boundaries of professional practice when prescribing for recurrent or persistent chronic pain. The prescribing guidelines for acute pain would be appropriately less stringent but, in principle, the same.

Guidelines

The Kentucky Board of Medical Licensure has adopted the following guidelines when evaluating the use of controlled substances for control of recurrent or chronic pain.

1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical record. A family history should be documented with particular reference to any history of first degree relative with chemical dependence problems. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of any substance abuse. The medical record also should document the presence of one or more recognized medical indication(s) for the use of a controlled substance.

By definition, pain is a *subjective* statement of a patient's perception of actual or potential tissue damage. The distinction between pain and suffering should be established. A patient may suffer due to pain, but may have other reasons for suffering as well. The assessment of a patient's overall condition should be made at the initial evaluation and thereafter. It is the goal of the physician to assist in the relief of suffering no matter the cause. Financial, emotional, mental, physical, and spiritual factors may contribute to the patient's suffering. Relief of the underlying reasons for suffering as well as the pain will lead to optimal treatment and utilization of controlled substances.

Before beginning a regimen of controlled drugs, the physician must determine, through actual clinical trial or through patient records and history that non-addictive medication regimens have been inadequate or are unacceptable for solid clinical reasons. Speaking with the patient's significant other or conducting a family conference can be helpful if there is any doubt regarding the patient's integrity. Utilizing the Kentucky All Schedule Prescription Electronic Reporting [i.e., KASPER Report] initially can also aid in documenting the patient's history of drug utilization.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Acknowledges the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(-) *CRITERION 9:*
Opioids are a last resort

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations, consultations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consents and Treatment Agreements

The physician should discuss the risks and benefits of the use of controlled substances with the patient or his / her surrogate, including the risk of tolerance and drug dependence. If the patient is determined to be at *high risk* for medication abuse or has a history of substance abuse, the physician may employ the use of a written *agreement* between physician and patient outlining patient responsibilities, including:

- One prescribing doctor and one designated pharmacy.
- Urine / serum drug screening when requested.
- No early refills and no medications called in. If medications are lost or stolen, then a police report could be required before considering additional prescriptions.
- The reasons for which drug therapy may be is continued such as violation of a documented doctor-patient *agreement*.

4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as reduction in patient's pain intensity and improved physical and / or psychosocial function (i.e., ability to work), need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans. Periodic requests for a **KASPER Report** could be utilized.

5. Consultation

The physician should be willing to refer the patient as clinically indicated for additional evaluation and in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a coexisting psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

(CONTINUED ON NEXT PAGE)

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

6. Medical Records

The physician should keep accurate and complete records, to include:

The medical history and physical examination;
Diagnostic, therapeutic, and laboratory results;
Evaluations and consultations;
Treatment objectives;
Discussion of risk, benefits, and limitation of treatments;
Treatments;
Medications (including date, type, dosage, and quantity prescribed);
Instructions and agreements;
Periodic reviews; and
Records should remain current and be maintained in an accessible manner and readily available for review.

Initial or periodic **KASPER Report(s)** should not be part of the patient's records and should not be released to the patient or a third party.

7. Compliance with Controlled Substances Laws and Regulations

To prescribe, dispense, or administer controlled substances, the physician must have an active license in the state and comply with applicable federal and state regulations. Kentucky physicians can refer to prior Board-published recommendations for prescribing Scheduled II drugs including opioids[3], benzodiazepines[4], and stimulants[5].

Physicians should studiously **avoid** prescribing scheduled drugs for themselves, immediate family, or staff in accordance with the American Medical Association's Code of Medical Ethics and the KRS Medical Practice Act.

Conclusion

By publishing these guidelines, the KBML wishes to encourage Kentucky physicians to utilize adequate medications to treat their patients with serious pain complaints without undue fear of legal or licensure repercussions. Concurrently, the Board strives to prevent as much as possible, drug diversion and inappropriate prescribing practices.

KENTUCKY

STATUTES

Suicide Assistance

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

KRS § 216.304

§ 216.304. Actions of licensed health care professional that are not violative of KRS 216.302

(1) A licensed health care professional who administers, prescribes, or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, shall not be deemed to have violated KRS 216.302 unless the medications or procedures are knowingly and intentionally administered, prescribed, or dispensed to cause death.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

LA

LOUISIANA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 40. Public Health and Safety; Chapter 4. Food and Drugs; Part 10. Uniform Controlled Substances Law

- MEDICAL PRACTICE ACT *(No provisions found)*
  Title 37. Professions and Occupations; Chapter 15. Physicians, Surgeons, and Midwives

- PHARMACY PRACTICE ACT
  Title 37. Professions and Occupations; Chapter 14. Louisiana Pharmacy Practice Act

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) *(No provisions found)*
  Title 46. Professional and Occupational Standards; Part LIII. Pharmacists; Chapter 35. Pharmacy Prescription Drugs

- MEDICAL BOARD REGULATIONS
  Title 46. Professional and Occupational Standards; Part XLV. Medical Professions

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 46. Professional and Occupational Standards; Part LIII. Pharmacists

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- SUICIDE
  Title 14. Criminal Law; Chapter 1. Criminal Code; Part 2. Offenses Against the Person; Subpart A-2. Suicide

- PAIN MANAGEMENT CLINICS
  Title 40. Public Health and Safety; Chapter 11. State Department of Hospitals; Part 12-A. Pain Management Clinics

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●				●	●
Medical Practice Act[1]								
Pharmacy Practice Act			●					
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board		●	●				●	●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Suicide								●
Pain Management Clinics[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board	●	●						
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Suicide[1]								
Pain Management Clinics				●				●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

La. R.S. 40:961

§ 40:961. Definitions

As used in this Part, the following terms shall have the meaning ascribed to them in this Section unless the context clearly indicates otherwise:

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(18) "Drug dependent person" means a person who is using a controlled dangerous substance and who is in a state of psychic or physical dependence, or both, arising from administration of that controlled dangerous substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects, or to avoid the discomfort of its absence.

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(31) "Practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled dangerous substance in the course of professional practice or research in this state.

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(38) "Substance abuse" or "addiction" means a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological, or physical consequences, the continued use of which results in a decreased quality of life. The development of controlled dangerous substance tolerance or physical dependence does not equate with substance abuse or addiction.

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La. R.S. 40:1002

§ 40:1002. Purpose

The purpose of this Part is to authorize the development, implementation, operation, and evaluation of an electronic system for the monitoring of controlled substances and other drugs of concern that are dispensed in the state or dispensed to an address within the state. The goal of the program is to improve the state's ability to identify and inhibit the diversion of controlled substances and drugs in an efficient and cost-effective manner and in a manner that shall not impede the appropriate utilization of these drugs for legitimate medical purposes.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

La. R.S. 37:1164

§ 37:1164. Definitions

As used in this Chapter, the following terms have the meaning ascribed to them by this Section:

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(42) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate licensing board to prescribe and administer drugs in the course of professional practice.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

LAC 46:XLV 6915-6923 (non-seq)

§ 6915. Scope of Subchapter

The rules of this subchapter govern physician responsibility for providing effective and safe pain control for patients with noncancer-related chronic or intractable pain.

§ 6917. Definitions

As used in this subchapter, unless the content clearly states otherwise, the following terms and phrases shall have the meanings specified:

Board--the Louisiana State Board of Medical Examiners.

Chronic Pain--pain which persists beyond the usual course of a disease, beyond the expected time for healing from bodily trauma, or pain associated with a long-term incurable or intractable medical illness or disease.

Controlled Substance--any substance defined, enumerated, or included in federal or state statute or regulations 21 C.F.R. §§ 1308.11-15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such regulations and statute.

Diversion--the conveyance of a controlled substance to a person other than the person to whom the drug was prescribed or dispensed by a physician.

Intractable Pain--a chronic pain state in which the cause of the pain cannot be eliminated or successfully treated without the use of controlled substance therapy and, which in the generally accepted course of medical practice, no cure of the cause of pain is possible or no cure has been achieved after reasonable efforts have been attempted and documented in the patient's medical record.

(-) CRITERION 10: ***Implies opioids are not part of professional practice***

Noncancer-Related Pain--that pain which is not directly related to symptomatic cancer.

Physical Dependence–the physiological state of neuroadaptation to controlled substance which is characterized by the emergence of a withdrawal syndrome if the controlled substance use is stopped or decreased abruptly, or if an antagonist is administered. Withdrawal may be relieved by readministration of the controlled substance.

Physician--physicians and surgeons licensed by the Board.

Protracted Basis--utilization of any controlled substance for the treatment of noncancer-related chronic or intractable pain for a period in excess of 12 weeks during any 12-month period.

Substance Abuse (may also be referred to by the term Addiction)– a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological, and/or physical consequences, the continued use of which results in a decreased quality of life. The development of controlled substance tolerance or physical dependence does not equate with substance abuse or addiction.

(+) CRITERION 7: ***Physical dependence or analgesic tolerance are not confused with "addiction"***

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Tolerance–refers to the physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose. Controlled substance tolerance refers to the need to increase the dose of the drug to achieve the same level of analgesia. Controlled substance tolerance may or may not be evident during controlled substance treatment.

§ 6919. General Conditions/Prohibitions

The treatment of noncancer-related chronic or intractable pain with controlled substances constitutes legitimate medical therapy when provided in the course of professional medical practice and when fully documented in the patient's medical record. A physician duly authorized to practice medicine in Louisiana and to prescribe controlled substances in this state shall not, however, prescribe, dispense, administer, supply, sell, give, or otherwise use for the purpose of treating such pain, any controlled substance unless done in strict compliance with applicable state and federal laws and the rules enumerated in this subchapter.

§ 6921. Use of Controlled Substances, Limitations

A. Requisite Prior Conditions. In utilizing any controlled substance for the treatment of noncancer-related chronic or intractable pain on a protracted basis, a physician shall comply with the following rules:

1. Evaluation of the Patient. Evaluation of the patient shall initially include relevant medical, pain, alcohol and substance abuse histories, an assessment of the impact of pain on the patient's physical and psychological functions, a review of previous diagnostic studies, previously utilized therapies, an assessment of coexisting illnesses, diseases, or conditions, and an appropriate physical examination.

2. Medical Diagnosis. A medical diagnosis shall be established and fully documented in the patient's medical record, which indicates not only the presence of noncancer-related chronic or intractable pain, but also the nature of the underlying disease and pain mechanism if such are determinable.

3. Treatment Plan. An individualized treatment plan shall be formulated and documented in the patient's medical record which includes medical justification for controlled substance therapy. Such plan shall include documentation that other medically reasonable alternative treatments for relief of the patient's noncancer-related chronic or intractable pain have been considered or attempted without adequate or reasonable success. Such plan shall specify the intended role of controlled substance therapy within the overall plan, which therapy shall be tailored to the individual medical needs of each patient.

4. Informed Consent. A physician shall ensure that the patient and/or his guardian is informed of the benefits and risks of controlled substance therapy. Discussions of risks and benefits should be noted in some format in the patient's record.

B. Controlled Substance Therapy. Upon completion and satisfaction of the conditions prescribed in §6921.A, and upon a physician's judgment that the prescription, dispensation, or administration of a controlled substance is medically warranted, a physician shall adhere to the following rules.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(-) *CRITERION 9:*
Opioids are a last resort

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

1. Assessment of Treatment Efficacy and Monitoring. Patients shall be seen by the physician at appropriate intervals, not to exceed 12 weeks, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, and evaluate the patient's progress toward treatment objectives and any adverse drug effects. Exceptions to this interval shall be adequately documented in the patient's record. During each visit, attention shall be given to the possibility of decreased function or quality of life as a result of controlled substance treatment. Indications of substance abuse or diversion should also be evaluated. At each visit, the physician should seek evidence of under treatment of pain.

2. Drug Screen. If a physician reasonably believes that the patient is suffering from substance abuse or that he is diverting controlled substances, the physician shall obtain a drug screen on the patient. It is within the physician's discretion to decide the nature of the screen and which type of drug(s) to be screened.

3. Responsibility for Treatment. A single physician shall take primary responsibility for the controlled substance therapy employed by him in the treatment of a patient's noncancer-related chronic or intractable pain.

4. Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

5. Medications Employed. A physician shall document in the patient's medical record the medical necessity for the use of more than one type or schedule of controlled substance employed in the management of a patient's noncancer-related chronic or intractable pain.

6. Treatment Records. A physician shall document and maintain in the patient's medical record, accurate and complete records of history, physical and other examinations and evaluations, consultations, laboratory and diagnostic reports, treatment plans and objectives, controlled substance and other medication therapy, informed consents, periodic assessments, and reviews and the results of all other attempts at analgesia which he has employed alternative to controlled substance therapy.

7. Documentation of Controlled Substance Therapy. At a minimum, a physician shall document in the patient's medical record the date, quantity, dosage, route, frequency of administration, the number of controlled substance refills authorized, as well as the frequency of visits to obtain refills.

C. Termination of Controlled Substance Therapy. Evidence or behavioral indications of substance abuse or diversion of controlled substances shall be followed by tapering and discontinuation of controlled substance therapy. Such therapy shall be reinitiated only after referral to and written concurrence of the medical necessity of continued controlled substance therapy by an addiction medicine specialist, a pain management specialist, a psychiatrist, or other substance abuse specialist based upon his physical examination of the patient and a review of the referring physician's medical record of the patient.

§ 6923. Effect of Violation

Any violation of or failure of compliance with the provisions of this subchapter, §§6915-6923, shall be deemed a violation of R.S. 37:1285(A)(6) and (14), providing cause for the board to suspend or revoke, refuse to issue, or impose probationary or other restrictions on any license held or applied for by a physician to practice medicine in the state of Louisiana culpable of such violation.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

La. R.S. 14:32.12

§ 14:32.12. Criminal assistance to suicide

A. Criminal assistance to suicide is:

(1) The intentional advising or encouraging of another person to commit suicide or the providing of the physical means or the knowledge of such means to another person for the purpose of enabling the other person to commit or attempt to commit suicide.

(2) The intentional advising, encouraging, or assisting of another person to commit suicide, or the participation in any physical act which causes, aids, abets, or assists another person in committing or attempting to commit suicide.

B. For the purposes of this Section, "suicide" means the intentional and deliberate act of taking one's own life through the performance of an act intended to result in death.

C. The provisions of this Section shall not apply to any licensed physician or other authorized licensed health care professional who either:

(1) Withholds or withdraws medical treatment in accordance with the provisions of *R.S. 40:1299.58.8*.

(2) Prescribes, dispenses, or administers any medication, treatment, or procedure if the intent is to relieve the patient's pain or suffering and not to cause death.

D. Whoever commits the crime of criminal assistance to suicide shall be imprisoned, with or without hard labor, for not more than ten years or fined not more than ten thousand dollars, or both.

STATUTES

Pain Management Clinics

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY D:
Undue prescription limitations

COMMENT: Seems to create a treatment disparity for any patient treated in a licensed pain management clinic, since the 30-day limit on the quantity of medication is not a requirement for all patients.

La. R.S. 40:2198.12

§ 40:2198.12. Licensure of pain management clinics; rules and regulations

A. Except as provided in Subsection D of this Section, all pain management clinics shall be owned and operated by a physician certified in the subspecialty of pain management by a member board of the American Boards of Medical Specialties.

B. (1) The department shall prescribe and publish minimum standards, rules, and regulations as necessary to effectuate the provisions of this Section. Such rules and regulations shall include but not be limited to all of the following:

(a) Operational and personnel requirements.

(b) Practice standards to assure quality of care, including the requirement that prescriptions may be written for the medication to last a period of no longer than thirty days without any refills. A refill may be authorized only if the individual is personally examined by the pain specialist.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Seems to apply to all prescription medication, including Schedule II controlled substances which cannot be refilled under either federal or state law.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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MAINE

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT (*No provisions found*)
  Title 25. Internal Security and Public Safety; Part 8. Public Safety Miscellaneous Provisions; Chapter 353. Maine Drug Enforcement Act of 1992

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 32. Professions and Occupations; Chapter 48. Board of Licensure in Medicine

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Title 32. Professions and Occupations; Chapter 36. Osteopathic Physicians

- PHARMACY PRACTICE ACT
  Title 32. Professions and Occupations; Chapter 117. Maine Pharmacy Act

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Agency 16. Department of Public Safety; Sub-Agency 230. Maine Drug Enforcement Agency; Chapter 001. Requirements for Written Prescriptions of Schedule II Drugs

- MEDICAL BOARD REGULATIONS
  Agency 02. Department of Professional and Financial Regulation; Sub-Agency 373. Board of Licensure in Medicine

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Agency 02. Department of Professional and Financial Regulation; Sub-Agency 383. Osteopathic Licensure Board

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Agency 02. Department of Professional and Financial Regulation; Sub-Agency 392. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- PRESCRIPTION PRIVACY
  Title 22. Health and Welfare; Subtitle 2. Health; Part 4. Hospitals and Medical Care; Chapter 401. General Provisions

- CONTROLLED SUBSTANCES PRESCRIPTION MONITORING
  Title 22. Health and Welfare; Subtitle 4. Human Services; Part 3. Drug Abuse; Chapter 1603. Controlled Substances Prescription Monitoring

- HOSPICE LICENSING
  Title 22. Health and Welfare; Subtitle 6. Facilities for Children and Adults; Chapter 1681. Licensing of Hospice Programs

- HOSPICE LICENSING
  Agency 10. Department of Health and Human Services; Sub-Agency 144. General; Chapter 120. Regulations Governing the Licensing and Functioning of Hospice Programs

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act			●					
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board (Joint regulation)		●	●	●	●		●	●
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Prescription Privacy			●					
Controlled Substances Prescription Monitoring								●
Hospice Licensing								●
Hospice Licensing								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board (Joint regulation)[1]								
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Prescription Privacy[1]								
Controlled Substances Prescription Monitoring[1]								
Hospice Licensing[1]								
Hospice Licensing[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

32 M.R.S. § 13702

§ 13702. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

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29. PRACTITIONER. "Practitioner" means an individual who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Joint Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

CMR 02-373-011

Jointly published as:

02 Department of Professional and Financial Regulation
383 Board of Osteopathic Licensure
011 Use of Controlled Substances for Treatment of Pain

02 373 011 Use of Controlled Substances for Treatment of Pain

Preamble: The Boards recognize that principles of quality medical practice dictate that the people of the State of Maine have access to appropriate and effective pain relief.

The Boards acknowledge that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery, and chronic pain, whether due to cancer or non-cancer origins. Fears of investigation by federal, state and local regulatory agencies should not preclude appropriate and adequate treatment of chronic pain patients. However, the Boards recognize that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use.

(+) *CRITERION 3:* *Opioids are part of professional practice*

(+) *CRITERION 2:* *Pain management is part of medical practice*

The Boards encourage physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and as especially important for patients who experience pain as a result of a terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(+) *CRITERION 5:* *Addresses fear of regulatory scrutiny*

(+) *CRITERION 4:* *Encourages pain management*

Accordingly, the Boards adopt these rules to clarify their positions on pain control and prescribing, specifically related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

§ 1. Definitions: As used by the Boards when evaluating practice and prescribing issues.

A. "Acute Pain" is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time limited and is responsive to controlled substances therapy, among other therapies.

B. "Addiction" is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(+) *CRITERION 7:* *Physical dependence or analgesic tolerance are not confused with "addiction"*

C. "Analgesic Tolerance" is the need to increase the dose of controlled substances to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

D. "Chronic Pain" is a pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

E. "Pain" is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

F. "Physical Dependence" on a controlled substance is a physiologic state of neuroadaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(CONTINUED ON NEXT PAGE)

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Joint Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

G. "Pseudoaddiction" is a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

H. "Substance Abuse" is the use of any controlled substance(s) for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.

I. "Tolerance" is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose.

§ 2. Principles of Proper Patient Management: Each of these principles is essential in the treatment of patients with pain.

A. Evaluation of the Patient: Evaluation should initially include a pain history and assessment of the impact of pain on the patient, a directed physical examination, a review of previous diagnostic studies, a review of previous interventions, a drug history, and an assessment of coexisting diseases or conditions.

B. Treatment Plan: Treatment planning should be tailored to both the individual and the presenting problem. Consideration should be given to different treatment modalities, such as a formal pain rehabilitation program, the use of behavioral strategies, the use of non-invasive techniques, or the use of medications, depending upon the physical and psychosocial impairment related to the pain. If a trial of controlled substances is selected, the physician should ensure that the patient or the patient's legally authorized representative is informed of the risks and benefits of controlled substance use and the conditions under which controlled substances will be prescribed. Some practitioners find a written agreement specifying these conditions to be useful. A controlled substances trial should not be done in the absence of a complete assessment of the pain complaint.

If the evaluation cannot be completed at the initial visit, controlled substances should only be prescribed in limited quantities, until completion of the evaluation, using the best judgment of the prescribing practitioner based on the information available.

In the instance of chronic end of life pain, please see Section 3.

C. Informed Consent and Agreement for Treatment: The physician should discuss treatment with the patient, persons designated by the patient, or with the patient's legally authorized representative if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy, where possible. If the patient is determined to be at high risk for medication abuse or has a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities. Suggested elements of such an agreement are provided in Appendix 1.

D. Consultation: The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Joint Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

E. Periodic review of treatment efficacy: Review of treatment efficacy should occur periodically to assess the functional status of the patient, continued analgesia, controlled substances side effects, quality of life and indications of medications abuse. Periodic re-examination is warranted to assess the nature of the pain complaint and to ensure that controlled substances therapy is still indicated. Attention should be given to the possibility of a decrease in global function or quality of life as a result of controlled substance abuse.

F. Documentation: Documentation is essential for supporting the evaluation, the reason for controlled substance prescribing, the overall pain management treatment plan, any consultations received, and periodic review of the status of the patient. The physician should document drug treatment outcomes and rationale for changes.

Every prescription must be clearly documented in the patient record. All written prescriptions must include name, address, drug name, amount prescribed, as well as instructions.

G. Reportable Acts: Information gained as part of the doctor/patient relationship, even if it gives knowledge of possible criminal acts, remains part of the confidential doctor/patient relationship. This needs to be contrasted with persons who use the physician to perpetrate illegal acts such as illegal acquisition or selling of drugs, etc. The physician has an obligation to deal with this behavior up to and including reporting to law enforcement. Reports from other providers, such as pharmacists and ER physicians, suggesting inappropriate or drug-seeking behavior, should be dealt with appropriately.

§ 3. The Principles of End of Life Pain Therapy:

In the instance of chronic end of life pain, a treatment plan which addresses the goals of comfort and personal dignity, developed at the time of original diagnosis is sufficient. Certain suggestions and considerations as noted in Section 2.2, 3, 4, & 5 may well not apply to this category of patient. Evaluation and documentation to ensure patient comfort and dignity as well as to manage other aspects of the underlying illness are expected to continue.

Appendix 1.

1. Controlled Substances Contract: Suggested elements of a controlled substance contract are as follows:

a) specifies that the physician is the single source of controlled substances;

b) may specify the pharmacy;

c) written, informed consent to release contract to local emergency departments and pharmacies;

d) if written consent is given for release to local emergency departments and/or pharmacies, consent is also being given to the other providers to report violations of the contract back to the physician,

e) specifies that if the physician becomes concerned that there has been illegal activity, the physician may notify the proper authorities;

f) if the physician has obtained a written release, ER personnel and other providers shall report violations of the contract back to the doctor who prescribed the controlled substance(s).

g) specifies that a violation of the contract will result in a tapering and discontinuation of the narcotics prescription;

h) specifies that a risk of chronic narcotics treatment is physical dependence (as defined);

i) specifies that a risk of chronic narcotics treatment is addiction (as defined);

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exempts patients with chronic end-of-life pain from the treatment considerations for patients with other types of chronic pain.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Prescription Privacy

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

22 M.R.S. § 1711-E

§ 1711-E. Confidentiality of prescription drug information

1. DEFINITIONS. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

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G-1. "Prescriber" means a person who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

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(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Controlled Substances Prescription Monitoring

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

22 M.R.S. § 7245

§ 7245. Legislative intent

It is the intent of the Legislature that the prescription monitoring program established pursuant to this chapter serve as a means to promote the public health and welfare and to detect and prevent substance abuse. This chapter is not intended to interfere with the legitimate medical use of controlled substances.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Hospice Licensing

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

22 M.R.S. § 8623

§ 8623. Rules

The department shall adopt rules in accordance with Title 5, chapter 375 that specify the requirements for licensure under this chapter. The rules must require, but are not limited to, the following provisions.

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7. TRAINING. A hospice program shall provide an educational program that offers a comprehensive overview of hospice philosophy and hospice care. A minimum of 18 hours of education, including 4 hours of orientation, is required for all direct service providers delivering hospice care. The educational program must include, but is not limited to, the following subjects:

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C. Pain and symptom management;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (training) for hospices to ensure that pain management is an essential part of patient care.

REGULATIONS

Hospice Licensing

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

CMR 10-144-120

10 144 120 Regulations Governing the Licensing and Functioning of Hospice Programs

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5.G. Training

A hospice program shall provide an educational program that offers a comprehensive overview of hospice philosophy and hospice care. A minimum of eighteen (18) hours of education, including four (4) hours of orientation, is required for all direct service providers delivering hospice care. The educational program must include, but is not limited to, the following subjects:

5.G.1. Hospice philosophy,

5.G.2. Family dynamics;

5.G.3. Pain and symptom management;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (educational program) for hospices to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MD

MARYLAND

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Criminal Law; Title 5. Controlled Dangerous Substances, Prescriptions, and Other Substances

- MEDICAL PRACTICE ACT (*No provisions found*)
  Health Occupations; Title 14. Physicians

- PHARMACY PRACTICE ACT (*No provisions found*)
  Health Occupations; Title 12. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 10. Department of Health and Mental Hygiene;
  Subtitle 13. Drugs; Chapter 01. Dispensing of Prescription Drugs by a Licensee
  Subtitle 19. Dangerous Devices and Substances; Chapter 03. Controlled Dangerous Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 10. Department of Health and Mental Hygiene; Subtitle 32. Board of Physicians

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 10. Department of Health and Mental Hygiene; Subtitle 34. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Maryland Board of Physicians. *Prescribing Controlled Substances*. Maryland BPQA Newsletter. Vol. 4, No. 1, pp. 1-3. Adopted: March, 1996.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- ASSISTED SUICIDE
  Criminal Law; Title 3. Other Crimes Against the Person; Subtitle 1. Assisted Suicide

- RIGHTS OF INDIVIDUALS
  Health-General; Title 19. Health Care Facilities; Subtitle 3. Hospitals and Related Institutions; Part IV. Rights of Individuals

- HOSPICE CARE PROGRAMS
  Title 10. Department of Health and Mental Hygiene; Subtitle 07. Hospitals; Chapter 21. Hospice Care Programs

MD

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act	●		●					●
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline					●		●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Assisted Suicide								●
Rights of Individuals								●
Hospice Care Programs								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

MD

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances								●
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Assisted Suicide[1]								
Rights of Individuals[1]								
Hospice Care Programs[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

MARYLAND

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Md. CRIMINAL LAW Code Ann. § 5-101

§ 5-101. Definitions

(a) In general. -- In this title the following words have the meanings indicated.

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(d) Authorized provider. --

(1) "Authorized provider" means:

(i) a person licensed, registered, or otherwise allowed to administer, distribute, dispense, or conduct research on a controlled dangerous substance in the State in the course of professional practice or research;

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(n) Drug dependent person. -- "Drug dependent person" means a person who:

(1) is using a controlled dangerous substance; and

(2) is in a state of psychological or physical dependence, or both, that:

(i) arises from administration of that controlled dangerous substance on a continuous basis; and

(ii) is characterized by behavioral and other responses that include a strong compulsion to take the substance on a continuous basis in order to experience its psychological effects or to avoid the discomfort of its absence.

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Md. CRIMINAL LAW Code Ann. § 5-102

§ 5-102. Legislative findings and purpose of title

(a) Findings. -- The General Assembly finds that:

(1) many of the substances listed in this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the people of the State; but

(2) the illegal manufacture, distribution, possession, and administration of controlled dangerous substances have a substantial and detrimental effect on the health and general welfare of the people of the State.

(b) Purpose. --

(1) The purpose of this title is to establish a uniform law to control the manufacture, distribution, possession, and administration of controlled dangerous substances and related paraphernalia to:

(i) ensure their availability for legitimate medical and scientific purposes; but

(ii) prevent their abuse, which results in a serious health problem to the individual and represents a serious danger to the welfare of the people of the State.

(2) This title shall be liberally construed to accomplish this purpose.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

(+) *CRITERION 1:*
Controlled substances are necessary for public health

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MARYLAND

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

COMAR 10.19.03.02

.02 Definitions.

A. As used in this chapter, unless otherwise provided, those definitions appearing in *Criminal Law Article, § 5-101*, Annotated Code of Maryland, shall apply.

B. In this chapter, the following terms have the meanings indicated.

C. Terms Defined.

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(7) Individual Practitioner.

(a) "Individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States or the jurisdiction in which the individual practitioner practices, to dispense a controlled dangerous substance in the course of professional practice.

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COMAR 10.19.03.07

.07 Prescriptions.

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F. Administering or Dispensing of Narcotic Drugs (*21 CFR § 1306.07*).

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(3) A physician or authorized hospital staff may administer or dispense narcotic drugs:

(a) In a hospital to maintain or detoxify an individual as an incidental adjunct to medical or surgical treatment of conditions other than addiction; or

(b) To an individual with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Does this imply that opioids are a treatment of last resort?

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

PRESCRIBING CONTROLLED SUBSTANCES

In a recent AMA survey of physicians, the majority of physicians responding reported that their prescribing of controlled drugs was negatively influenced by a fear of licensing board sanctions. The issue of prescribing adequate pain medication for the terminally ill, generally patients with cancer, has received extensive attention. But what about patients with chronic noncancer pain? Little has been done to alleviate physician anxiety that regularly prescribing controlled drugs to such patients will result in the physician being accused of diverting drugs illegally or supporting addictive patients in their habits. How can a physician both meet their patients' needs and avoid coming to the attention of the licensing authorities?

BPQA, by statute, has a minimum of eleven Board members who are actively practicing physicians. We see these patients in our offices, too, and we recognize that there are many painful conditions which cannot be cured and that diagnoses may be totally based on subjective symptoms. As physicians, our role is to relieve suffering; we may have no hard evidence that "proves" the patient is in pain, yet we believe our patients and we try to help them. All the members of BPQA wish to reassure Maryland physicians that they need not under-prescribe needed medications for fear of Board action. Under-prescribing results in unnecessary suffering.

(+) ***CRITERION 5:*** ***Addresses fear of regulatory scrutiny***

But what about all those Board actions you've read about in which the doctors are sanctioned for "inappropriate" controlled dangerous substance prescribing practices? Were these physicians just trying to alleviate suffering with the end result that the Board sanctioned them? Hardly. Most of the physicians charged under this provision of the Medical Practice Act were clearly acting in other than the best interest of their patients. Usually, obvious addicts were buying prescriptions from the physicians and the transactions were disguised as office visits. Occasionally, truly naive physicians, once they have been targeted as "easy writes," attract every addict in town. All of us in practice occasionally have been duped by a patient in this way. But some physicians simply don't recognize addiction. Usually, in addition to inappropriate prescribing, we find that the physician's practice is substandard in multiple other areas. It is rare that an otherwise well-trained and competent physician is identified as a naive prescriber.

Because the Board is concerned that fear of disciplinary action may lead to inappropriately restrictive prescribing of controlled drugs, the following guidelines are offered by Dr. Charles Hobelmann Jr., who has served on the Board since 1991. Although the primary focus of his remarks is analgesic prescribing, these guidelines can be applied to every prescribing and treatment situation. It's just good medical practice spelled out, and it's how the Board evaluates the delivery of all medical care, not just controlled drug prescribing. His comments follow.

In order to help the physicians whose patients may require long-term analgesic medications, a common sense approach coupled with experience and medical knowledge is essential. It is important to realize that habituation and tolerance to drugs are not the same as addiction. These are expected consequences of long-term analgesic therapy and do not have the characteristics of sociopathy and psychologic dependence associated with addiction. Whereas it is inappropriate to prescribe analgesics to maintain addiction, it is good medical care to provide relief from chronic pain even in the face of habituation and tolerance. Some general guidelines may be helpful both in the management of these patients and in protecting one's self from legal or Board action in prescribing for them. The following comments have been adapted from published material of the Medical Board of California and provide a useful guide in this area.

(CONTINUED ON NEXT PAGE)

(+) ***CRITERION 7:*** ***Physical dependence or analgesic tolerance are not confused with "addiction"***

COMMENT*:* However, it is preferable to substitute "physical dependence" for the archaic term "habituation."

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MARYLAND

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

History and Physical Generally speaking, it is improper to prescribe any medication for any patient without first taking the steps essential to evaluation. This is particularly true of the chronic pain patients because other treatment modalities may be beneficial and because it is important to recognize the addict who may complain of pain as a means to maintain a habit. Prescribing narcotics without a documented evaluation always represents substandard care.

Treatment Plan Just as treatment for diabetes or hypertension has a specific objective, so should treatment for chronic pain. Frequently, the pain cannot be completely relieved but the use of analgesic drugs may lead to an improved sense of well-being, better sleep or even a return to work. The goal of analgesic therapy should be documented and the patient's progress measured against this goal.

Informed Consent Since long-term narcotic use will usually result in habituation and tolerance, these risks should be discussed with the patient. Alternatives should be offered if they exist and the clinical record should refer to the discussion.

Periodic Review The course of treatment and the meeting of therapeutic goals should be periodically reviewed as is the case with any patient suffering from chronic disease. Modification of treatment or its discontinuation should be considered depending upon how well goals are being met. New information about the etiology of the pain or its treatment should be evaluated.

Consultation The complexity of chronic pain frequently requires evaluation by consultants who may suggest alternatives or additions to therapy. This may be particularly true in the patient who is at risk for drug misuse. The patient with a history of substance abuse requires special care in documentation, evaluation and consultation before long-term opiate treatment can be safely prescribed. Some pain management specialists recommend a written agreement with these and other patients before such therapy.

Records Adequate documentation is the key to management of these difficult patients and is the key to protecting the physician from legal or Board action. Documentation of the steps noted above should be recorded in a fashion that would allow another practitioner to understand and follow through with treatment.

Finally, the physician who uses scheduled drugs should be familiar with federal and local laws regulating their use. The U.S. Drug Enforcement Administration publishes a physicians' manual and Maryland laws are available through the Board. The Board hopes that physicians will use these guidelines to help them manage patients with chronic pain without fear of regulatory scrutiny. At the same time, the Board maintains its commitment to prevent the diversion and abuse of controlled substances.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MARYLAND

STATUTES

Assisted Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Md. CRIMINAL LAW Code Ann. § 3-101

§ 3-103. Exceptions

(a) Palliative care -- Pain relief. -- A licensed health care professional does not violate § 3-102 of this subtitle by administering or prescribing a procedure or administering, prescribing, or dispensing a medication to relieve pain, even if the medication or procedure may hasten death or increase the risk of death, unless the licensed health care professional knowingly administers or prescribes the procedure or administers, prescribes, or dispenses the medication to cause death.

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STATUTES

Rights of Individuals

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Md. HEALTH-GENERAL Code Ann. § 19-342

§ 19-342. Hospitals

(a) Patient's bill of rights. -- Each administrator of a hospital is responsible for making available to each patient in the hospital a copy of the patient's bill of rights that the hospital adopts under the Joint Commission on Accreditation of Hospitals' guidelines.

(b) Same -- Statement. -- The patient's bill of rights shall include a statement that a patient has a right to expect and receive appropriate assessment, management, and treatment of pain as an integral component of the patient's care.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospitals to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospice Care Programs

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

COMAR 10.07.21.13

.13 Physician Services.

A. Medical Director. The hospice care program shall have a medical director who shall be:

(1) A physician licensed to practice medicine in this State; and

(2) Knowledgeable about the psychosocial and medical aspects of hospice care.

B. Medical Director Duties. The medical director is responsible for:

(1) Reviewing, coordinating, and managing the clinical and medical care for all patients in the hospice care program;

(2) Consulting with attending physicians regarding pain and symptom control;

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.21 Patient's Rights.

A. The hospice care program shall provide the patient or representative with a written notice of the patient's rights in advance of furnishing care. Documentation verifying receipt of and understanding of this information shall be included as part of the patient's record.

B. The patient has the right to:

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(9) Be informed of short-term inpatient care options available for pain control, management, and respite;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes mechanisms for hospices to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MA

MASSACHUSETTS

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Part 1. Administration of the Government; Title XV. Regulation of Trade; Chapter 94C. Controlled Substances Act

- MEDICAL PRACTICE ACT (*No provisions found*)
  Part 1. Administration of the Government; Title XVI. Public Health; Chapter 112. Registration of Certain Professions and Occupations; Registration of Physicians and Surgeons

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Part 1. Administration of the Government; Title XVI. Public Health; Chapter 112. Registration of Certain Professions and Occupations; Osteopathy

- PHARMACY PRACTICE ACT (*No provisions found*)
  Part 1. Administration of the Government; Title XVI. Public Health; Chapter 112. Registration of Certain Professions and Occupations; Registration of Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 105. Department of Public Health; Chapter 701.000. Regulations Adopted Jointly by the Department of Public Health and the Board of Registration in Pharmacy for the Implementation of M. G. L. c. 94C

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 243. Board of Registration in Medicine

- PHARMACY BOARD REGULATIONS
  Title 247. Board of Registration in Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Massachusetts Board of Registration in Medicine. *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: December 15, 2004.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- DUTIES OF THE DEPARTMENT OF PUBLIC HEALTH
  Part 1. Administration of the Government; Title XVI. Public Health; Chapter 111. Public Health

- HOSPITAL LICENSURE
  Title 105. Department of Public Health; Chapter 130.000. Hospital Licensure; Subpart D. Supplementary Standards: Particular Services

- HOSPICE LICENSURE
  Title 105. Department of Public Health; Chapter 141.000. Licensure of Hospice Programs; Subpart B. General Requirement; Administration

MA

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act		●	●					
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					●
Medical Board[1]								
Pharmacy Board			●					
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Duties of the Department of Public Health								●
Hospital Licensure								●
Hospice Licensure								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

MA

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act				●				
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Duties of the Department of Public Health[1]								
Hospital Licensure[1]								
Hospice Licensure[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

MASSACHUSETTS

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

LM GL ch. 94C, § 1

§ 1. Definitions.

As used in this chapter, the following words shall, unless the context clearly requires otherwise, have the following meanings:

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"Practitioner",

(a) A physician, dentist, veterinarian, podiatrist, scientific investigator, or other person registered to distribute, dispense, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in the commonwealth.

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(+) *CRITERION 3:* *Opioids are part of professional practice*

Mass. Ann. Laws ch. 94C, § 9

§ 9. Authorized Possession, Administration and Dispensation of Controlled Substances; Records.

(a) A physician, dentist, podiatrist, optometrist as limited by sections 66 and 66B of chapter 112 and paragraph (h) of section 7, nurse practitioner and psychiatric nurse mental health clinical specialist as limited by paragraph (g) of said section 7 and section 80E of said chapter 112, physician assistant as limited by said paragraph (g) of said section 7 and section 9E of said chapter 112, a certified nurse-midwife as provided in section 80C of said chapter 112 or a veterinarian when registered pursuant to the provisions of said section 7 and acting in accordance with the provisions of applicable federal law and any provision of this chapter which is consistent with federal law, in good faith and in the course of a professional practice for the alleviation of pain and suffering or for the treatment or alleviation of disease, may possess such controlled substances as may reasonably be required for the purpose of patient treatment and may administer controlled substances or may cause the same to be administered under his direction by a nurse.

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(+) *CRITERION 2:* *Pain management is part of medical practice*

Mass. Ann. Laws ch. 94C, § 23

§ 23. Further Regulation of Prescriptions.

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(-) *CRITERION 12:* *Medical decisions are restricted*

CATEGORY C*: *Restrictions regarding quantity prescribed or dispensed

(d) In regard to a controlled substance in Schedule II or III, no prescription shall be filled for more than a thirty-day supply of such substance upon any single filling; provided, however, that with regard to dextro amphetamine sulphate and methyl phenidate hydrochloride, a prescription may be filled for up to a sixty-day supply of such substance upon any single filling if said substance is being used for the treatment of minimal brain dysfunction or narcolepsy; provided further, that subject to regulations of the department and the board of pharmacy, prescriptions for implantable infusion pumps consisting of Schedule II or Schedule III controlled substances may be filled for a maximum of 90 days.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MASSACHUSETTS

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

105 CMR 700.001

700.001: Definitions

For the purpose of *105 CMR 700.000*, the following definitions apply, in addition to those definitions appearing in *M.G.L. c. 94C, § 1*, unless the context or subject matter requires a different meaning.

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Practitioner means

(a) A physician, dentist, veterinarian, podiatrist, scientific investigator or other person registered to distribute, dispense, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in the commonwealth;

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105 CMR 700.006

700.006: Requirements for Records, Inventories, and Reports

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(3) Prescription Monitoring Program Medical Review Group.

(a) The Commissioner shall establish Prescription Monitoring Program Medical Review Groups, to provide accepted medical practice standards for the implementation of *105 CMR 700.006(J)* and related regulations. The membership of each Medical Review Group shall consist of two or more registered practitioners, one of whom shall be affiliated with a health care facility, and at least one registered pharmacist. In all cases, members of the Medical Review Groups shall be registered health care practitioners and a majority shall be registered in the same discipline as the practitioner whose records are under review. Registered practitioners shall be designated by the Commissioner from lists approved by the appropriate Boards of Registration in the discipline under which records will be reviewed. Such lists shall be provided by the respective statewide professional societies, whose membership shall fully represent the complete geographic and practice differences represented in the state as a whole.

1. In the event that insufficient listings are available to comprise the appropriate membership of any particular Medical Review Group, the Commissioner may appoint additional members.

2. Whenever possible, the practitioners on a particular Medical Review Group shall be specialists, as designated by a national accrediting board acceptable to the Commissioner, in the same field as the practitioner whose records are being reviewed.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (review by medical review group members with the same professional license) to assist in the evaluation of prescription monitoring program information.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MASSACHUSETTS

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

247 CMR 2.00

2.00: Definitions

Additional definitions pertaining to:

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Practitioner means any person with prescriptive privileges as defined in *M.G.L. c. 94C, § 1*. (by reference: A physician, dentist, veterinarian, podiatrist, scientific investigator or other person registered to distribute, dispense, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in the commonwealth;)

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(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Federation of State Medical Boards of the United States, Inc.

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., May 2004

Introduction

The Federation of State Medical Boards (the Federation) is committed to assisting state medical boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the Federation undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policy encouraging adequate treatment, including use of opioids when appropriate for patients with pain. The Federation thanks the Robert Wood Johnson Foundation for awarding a grant in support of the original project, and the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine, & Ethics, and the University of Wisconsin Pain & Policy Studies Group for their contributions.

Since adoption in April 1998, the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The *Model Guidelines* have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the *Model Guidelines*. [1] Despite increasing concern in recent years regarding the abuse and diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated. Many terminally ill patients unnecessarily experience moderate to severe pain in the last weeks of life.[2] The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in state pain policies.[3] Circumstances that contribute to the prevalence of undertreated pain include: (1) lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of addiction and dependence; and (4) lack of understanding of regulatory policies and processes. Adding to this problem is the reality that the successful implementation of state medical board pain policy varies among jurisdictions.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

In April 2003, the Federation membership called for an update to its *Model Guidelines* to assure currency and adequate attention to the undertreatment of pain. The goal of the revised model policy is to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The title of the policy has been changed from *Model Guidelines* to *Model Policy* to better reflect the practical use of the document.

The *Model Policy* is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. This policy is not meant to constrain or dictate medical decision-making.

Through this initiative, the Federation aims to achieve more consistent policy in promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of regulatory scrutiny. In promulgating this *Model Policy*, the Federation strives to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion.

State medical boards are encouraged, in cooperation with their state's attorney general, to evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. Accordingly, this *Model Policy* has been revised to emphasize the professional and ethical responsibility of the physician to assess patients' pain as well as to update references and definitions of key terms used in pain management.

The *Model Policy* is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations.

1. As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* and two (2) states have formally endorsed the *Model Guidelines*.

2. SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: *JAMA,* 274(20) (1995): p. 1591-1598.

3. A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, *J. of Law, Medicine, and Ethics*, 31 (2003): p. 128.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Identifies the possibility of restrictive policies as an important barrier to the appropriate use of opioid analgesics.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 4:*
Encourages pain management

(CONTINUED)

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble
The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

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(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines
The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

8. medications (including date, type, dosage and quantity prescribed),

9. instructions and agreements and

10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions
For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Duties of the Department of Public Health

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (palliative care program) to ensure that pain management is an essential part of care for pediatric patients.

ALM GL ch. 111, § 24K

§ 24K. Pediatric Palliative Care Program

There is hereby established the pediatric palliative care program. Said program shall be administered by the department, subject to appropriation, under this section and regulations promulgated hereunder. The program shall assist eligible children with a life-limiting illness and their families or guardians with services designed to achieve an improved quality of life and to meet the physical, emotional and spiritual needs experienced during the course of illness, death and bereavement.

Children less than 19 years of age shall be eligible for said program if they meet the requirements established by the department, which shall include:--

(a) a diagnosis of a life-limiting illness, including but not limited to, cancer, AIDS, congenital anomalies and other advanced illnesses; provided however, no requirement regarding life expectancy shall be imposed; and

(b) a requirement that the eligible child not be covered by a third-party payer for the services provided by said program.

Services provided by the program shall be determined by the department and shall include, but not be limited to, consultations for pain and symptom management, case management and assessment, social services, counseling, bereavement services, volunteer support services, and respite services, provided by professional or volunteer staff under professional supervision. Services shall be provided by hospice programs licensed under section 57D who meet such other criteria as the department may establish by regulation, including demonstrated expertise in pediatric palliative care. The department may by regulation establish limits on services provided by said program. The program established by this section shall not give rise to enforceable legal rights in any party or an enforceable entitlement to the services described in this section and nothing stated in this section shall be construed as giving rise to such enforceable legal rights or such enforceable entitlement.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MASSACHUSETTS

REGULATIONS

Hospital Licensure

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

105 CMR 130.616

130.616: Administration and Staffing

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(D) Patient Care Policies. Each maternal and newborn service shall develop and implement written patient care policies and procedures, supported by evidence based resources, which shall include provisions for the following:

(1) Triage of patents presenting to the service to establish the diagnosis of labor, need for admission, transfer and/or other care management.
(2) Communication and decision making responsibilities with specified chain of command.
(3) Pain management, including the use of non pharmacological support techniques, analgesic medication and parenteral therapy. Routine standing orders shall not be permitted.

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(12) Care of the Newborn. Such policies shall provide for the following:

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(i) Comfort measures and reduction of pain and trauma during invasive procedures.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written policies) for hospitals to ensure that pain management is an essential part of patient care.

REGULATIONS

Hospice Licensure

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

105 CMR 141.204

141.204: Required Patient Care Services

(1) Each hospice shall designate a physician to serve as Medical Director. The Medical Director shall have overall responsibility for the medical component of patient care and for ensuring achievement and maintenance of quality standards of professional medical care.

(2) The duties of the medical director shall include but need not be limited to:

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(k) Participating in establishing written programmatic guidelines for symptom control (*e.g.*, pain, nausea, vomiting, or other symptoms.)

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(H) Inpatient Care.

(1) The hospice shall provide or arrange for short-term inpatient care for the control of pain and management of acute and severe clinical problems that cannot be managed in a home setting.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written programmatic guidelines) for hospices to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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MICHIGAN

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Chapter 333. Health; Public Health Code; Article 7. Controlled Substances

- MEDICAL PRACTICE ACT
  Chapter 333. Health; Public Health Code; Article 15. Occupations; Part 170. Medicine

- OSTEOPATHIC PRACTICE ACT
  Chapter 333. Health; Public Health Code; Article 15. Occupations; Part 175. Osteopathic Medicine and Surgery

- PHARMACY PRACTICE ACT
  Chapter 333. Health; Public Health Code; Article 15. Occupations; Part 177. Pharmacy Practice and Drug Control

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Department of Community Health. Director's Office. Pharmacy - Controlled Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Department of Community Health. Director's Office. Medicine – General Rules

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Department of Community Health. Director's Office. Osteopathic Medicine and Surgery – General Rules

- PHARMACY BOARD REGULATIONS
  Department of Community Health. Director's Office. Board of Pharmacy – General Rules

OTHER GOVERNMENTAL POLICIES

- PHARMACY BOARD GUIDELINE
  Michigan Board of Pharmacy. *Michigan Board of Pharmacy Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted: ND.

- JOINT BOARD GUIDELINE
  Michigan Boards of Medicine and Osteopathic Medicine & Surgery. *Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted: Late 2003.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- END-OF-LIFE CARE
  Chapter 333. Health; Public Health Code; Article 5. Prevention and Control of Diseases and Disabilities; Part 56A. End-of-Life Care

- PROFESSIONAL PRACTICE
  Chapter 333. Health; Public Health Code; Article 15. Occupations; Part 161. General Provisions

- FACILITIES AND AGENCIES
  Chapter 333. Health; Public Health Code; Article 17. Facilities and Agencies

- HOSPICE AND HOSPICE RESIDENCES SERVICES
  Department of Consumer and Industry Services; Director's Office; Hospice and Hospice Residences; Part 3. Services

Provisions that may *ENHANCE* pain management

Criteria	1	2	3	4	5	6	7	8
	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with "addiction"	Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					●
Medical Practice Act								●
Osteopathic Practice Act								●
Pharmacy Practice Act								●
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board								●
OTHER GOVERNMENTAL POLICIES								
Pharmacy Board Guideline		●	●	●	●		●	●
Joint Board Guideline		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
End-of-Life Care		●			●			
Professional Practice		●	●	●				●
Facilities and Agencies								●
Hospice and Hospice Residence Services								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Pharmacy Board Guideline[1]								
Joint Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
End-of-Life Care[1]								
Professional Practice[1]								
Facilities and Agencies[1]								
Hospice and Hospice Residence Services[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

MCL § 333.7109

§ 333.7109. Definitions; P to U.

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(3) "Practitioner" means:

(a) A prescriber or pharmacist, a scientific investigator as defined by rule of the administrator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state, including an individual in charge of a dog pound or animal shelter licensed or registered by the department of agriculture pursuant to *1969 PA 287, MCL 287.331* to *287.340*, or a class B dealer licensed by the United States department of agriculture pursuant to the animal welfare act, Public Law 89-544, *7 U.S.C. 2131* to 2147, 2149, and 2151 to 2159 and the department of agriculture pursuant to *1969 PA 224, MCL 287.381* to *287.395*, for the limited purpose of buying, possessing, and administering a commercially prepared, premixed solution of sodium pentobarbital to practice euthanasia on animals.

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MCL § 333.7333a

§ 333.7333a. Electronic monitoring system.

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(7) The department, in consultation with the controlled substances advisory commission, the Michigan board of pharmacy, the Michigan board of medicine, the Michigan board of osteopathic medicine and surgery, the Michigan state police, and appropriate medical professional associations, shall examine the need for and may promulgate rules for the production of a prescription form on paper that minimizes the potential for forgery. The rules shall not include any requirement that sequential numbers, bar codes, or symbols be affixed, printed, or written on a prescription form or that the prescription form be a state produced prescription form. In examining the need for rules for the production of a prescription form on paper that minimizes the potential for forgery, the department shall consider and identify the following:

(a) Cost, benefits, and barriers.
(b) Overall cost-benefit analysis.
(c) Compatibility with the electronic monitoring system required under this section.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Recognizes characteristics of prescription monitoring programs that are believed to impede the appropriate medical use of Schedule II controlled substances.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

MCL § 333.17033

§ 333.17033. Renewal of license; continuing education requirements.

Sec. 17033. (1) Notwithstanding the requirements of part 161, the board may require a licensee seeking renewal of a license to furnish the board with satisfactory evidence that during the 3 years immediately preceding application for renewal the licensee has attended continuing education courses or programs approved by the board totaling not less than 150 hours in subjects related to the practice of medicine including, but not limited to, medical ethics and designed to further educate licensees.

(2) As required under section 16204, the board shall promulgate rules requiring each applicant for license renewal to complete as part of the continuing education requirement of subsection (1) an appropriate number of hours or courses in pain and symptom management.

STATUTES

Osteopathic Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MCL § 333.17533

§ 333.17533. Renewal of license; continuing education requirements.

Sec. 17533. (1) Notwithstanding the requirements of part 161, the board may require a licensee seeking renewal of a license to furnish the board with satisfactory evidence that during the 3 years immediately preceding an application for renewal the licensee has attended continuing education courses or programs approved by the board and totaling not less than 150 hours in subjects related to the practice of osteopathic medicine and surgery and designed to further educate licensees.

(2) As required under section 16204, the board shall promulgate rules requiring each applicant for license renewal to complete as part of the continuing education requirement of subsection (1) an appropriate number of hours or courses in pain and symptom management.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

MCL § 333.17731

§ 333.17731. Renewal of license; continuing education requirements.

Sec. 17731. (1) Notwithstanding the requirements of part 161, the board may require a licensee seeking renewal of a pharmacist's license to furnish the board with satisfactory evidence that during the 2 years immediately preceding application for renewal the applicant has attended continuing education courses or programs, approved by the board, totaling not less than 30 hours or the satisfactory completion of a proficiency examination according to rules promulgated by the board.

(2) As required under section 16204, the board shall promulgate rules requiring each applicant for license renewal to complete as part of the continuing education or proficiency examination requirement of subsection (1) an appropriate number of hours or courses in pain and symptom management.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MICHIGAN

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Mich. Admin. Code R 338.3170

R 338.3170 Dispensing and administering controlled substances by prescribers.

Rule 70. (1) A prescriber in the course of his or her professional practice only, may dispense or administer, or both, a controlled substance listed in schedules 2 to 5 or he or she may cause them to be administered by an assistant under personal charge supervision.

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(+) *CRITERION 3:*
Opioids are part of professional practice

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MICH. ADMIN. CODE R 338.3041

R 338.3041 Continuing education requirements; applicability.

Rule 1. (1) These rules apply to applications for renewal of a pharmacist's license. A renewal shall not be granted unless the applicant has fulfilled the requirements of these rules.

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(6) An applicant for license renewal shall complete in each renewal period at least 1 continuing education hour in pain management, as required under section 16204 of the code. This subrule takes effect July 1, 2007.

. . .

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (continuing education) to provide practitioners information/education about pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Pharmacy Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain

Michigan Board of Pharmacy Guidelines for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Michigan Board of Pharmacy recognizes that principles of quality pharmacy practice dictate that the people of the State of Michigan have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages pharmacists to view effective pain management as a part of quality health care for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All pharmacists should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing and dispensing controlled substances.

Inadequate pain control may result from a health care provider's lack of knowledge about pain management or from an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the position of the Board on pain control, specifically as related to the use of controlled substances, in order to alleviate uncertainty of pharmacists and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Pharmacists should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction. Pharmacists should also be aware that pseudoaddiction may develop as a direct consequence of inadequate pain management.

The Board is obligated under the laws of the State of Michigan to protect the public health and safety. The Board recognizes that inappropriate prescribing and dispensing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Pharmacists should be diligent in preventing the diversion of drugs for illegitimate purposes.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Pain management is encouraged

(+) CRITERION 7:
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies pseudoaddiction as an important barrier to the appropriate use of opioids analgesics.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Pharmacy Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

The following are reference sources that provide sound approaches to the management of pain:

1. Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. *Clinical Practice Guideline.* AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.

2. Jacox A, Carr DB, Payne R, et al. Management of Cancer Pain. *Clinical Practice Guideline No. 9.* AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. March 1994.

3. Lipman AG, *Pain Management for Primary Care Clinicians* . 1st ed. American Society of Health System Pharmacists: Bethesda. 2004.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Pharmacists should not fear disciplinary action from the Board or other state regulatory or enforcement agency for dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider control of patients' pain to constitute a legitimate medical purpose when the prescribing and dispensing of controlled substances is based on accepted scientific knowledge of the treatment of pain and/or when based on sound clinical grounds.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

The Board will not take disciplinary action against a pharmacist for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. In each case, the conduct of the pharmacist will be evaluated to a great extent by patient outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the patient's condition. In addition, the pharmacist will have taken steps in good faith to assure safe and effective medication use and to prevent possible drug diversion.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that efforts to reduce the abuse and diversion of controlled substances should not interfere with legitimate medical use.

Section II: Guidelines

The following guidelines are not intended to define complete or best practices, but rather to communicate what the Board considers to be minimum standards of practice for pharmacists caring for patients requiring pain control and presenting with prescriptions for controlled substances.

Review of the Prescription

The pharmacist should exercise due diligence to verify that each prescription for a controlled substance has been issued for a legitimate medical purpose. The review should include, but not necessarily be limited to, a careful review of the prescription document for evidence of forgery or alteration, a discussion with the patient regarding the signs and symptoms of the disorder or disease and the diagnosis, a review of the patient's prescription records, and/or a discussion with the prescriber. The pharmacist may also determine that a query to the Michigan Automated Prescription System (MAPS) is warranted if fraud is suspected. Each of these and/or other steps taken to assure the validity of a prescription should be documented and filed in a readily retrievable manner.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Pharmacy Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Fictitious or Possibly Fictitious Prescriptions

When a pharmacist is reasonably certain that a prescription is fictitious, he/she should contact the appropriate law enforcement agency. In cases where the pharmacist suspects, but cannot be certain, that a prescription is fictitious, he/she should take necessary steps to help assure that a patient's symptoms are managed during the time it takes to confirm the validity of the prescription. In these cases, the pharmacist should also be certain to obtain positive patient identification in case the event must later be reported to enforcement agencies. The pharmacist may also determine that a query to the Michigan Automated Prescription System (MAPS) is warranted.

Prescription Refills

The pharmacist should evaluate the patient at each refill of a controlled substance to help assure that positive, intended outcomes are achieved and that the patient is not experiencing untoward effects. This evaluation should include but not necessarily be limited to, a discussion with the patient regarding signs and symptoms of the condition being treated, a review of signs and symptoms of untoward effects, a review of the patient's prescription records, and/or a discussion with the prescriber regarding the need for continuation or modification of therapy.

Special attention should be given to those pain patients who are at risk for misusing their medications. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

The steps undertaken in the process of evaluation should be documented and filed in a readily retrievable manner.

Patient Referral

When a patient presents with a prescription for a controlled substance that is not stocked in the pharmacy, the pharmacist should make every effort to refer the patient to another proper source of care to help assure the patient finds access to medication required for symptom relief.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction
Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Pharmacy Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Analgesic Tolerance
Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain
A state of pain which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Controlled Substance
A controlled substance is a drug, substance, or immediate precursor included in schedules 1 to 5 of Article 7, part 72, of Public Act 368 of 1978 as amended (the Michigan Public Health Code).

Dispense
Dispense means to deliver or issue a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including prescribing, administering, or compounding necessary to prepare the substance for the delivery or issuance.

Dispenser
Dispenser means a practitioner that dispenses.

Good Faith
The prescribing or dispensing of a controlled substance by a practitioner licensed under section 333.7303 of the Michigan Public Health Code, in the regular course of professional treatment to, or for, an individual who is under treatment by a practitioner for a pathology or condition other than that individual's physical or psychological dependence upon or addiction to a controlled substance, except as provided in this article. Application of good faith to a pharmacist is the dispensing of a controlled substance pursuant to a prescriber's order that, in the professional judgment of the pharmacist, is lawful. The pharmacist shall be guided by nationally accepted professional standards including, but not limited to, all of the following, in making the judgment:

(a) Lack of consistency in the doctor-patient relationship
(b) Frequency of prescriptions for the same drug by one prescriber for larger numbers of patients
(c) Quantities beyond those normally prescribed for the same drug
(d) Unusual dosages
(e) Unusual geographic distances between patient, pharmacist, and prescriber.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Pharmacy Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Pharmacy Practice
Pharmacy practice means a health service, the clinical application of which includes the encouragement of safety and efficacy in the prescribing, dispensing, administering, and use of drugs and related articles for the prevention of illness, and the maintenance and management of health. Professional functions associated with the practice of pharmacy include:

(a) The interpretation and evaluation of the prescription
(b) Drug product selection
(c) The compounding, dispensing, safe storage, and distribution of drugs and devices.

Physical Dependence
Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Positive Identification
Positive identification means identification that includes a photograph of an individual in addition to his or her date of birth. Positive identification shall include an identification card issued by a governmental agency provided the ID card meets these requirements.

Practitioner
A prescriber or pharmacist, a scientific investigator as defined by rule or the administrator, or other person, licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of the professional practice or research in this state.

A pharmacy, hospital, or other institution or place of professional practice licensed, registered, or otherwise permitted to distribute, prescribe, dispense, conduct research with respect to, administer a controlled substance in the course of professional practice or research in this state.

Pseudoaddiction
Pseudoaddiction is the term that describes patient drug-seeking behaviors that may develop as a direct consequence of inadequate pain management. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Michigan Boards of Medicine and Osteopathic Medicine & Surgery recognize that principles of quality medical practice dictate that the people of the State of Michigan have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Boards' position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(+) *CRITERION 4:*
Encourages pain management

The Boards recognize that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the U.S. Agency for Health Care and Research Clinical Practice Guidelines for a sound approach to the management of acute (1) and cancer-related pain (2). The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The Boards are obligated under the laws of the State of Michigan to protect the public health and safety. The Boards recognize that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

1. Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.

2. Jacox A, Carr DB, Payne R, et al. Management of Cancer Pain. Clinical Practice Guideline No. 9. AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. March 1994.

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OTHER GOVERNMENTAL POLICY

Joint Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) CRITERION 5:
Addresses fear of regulatory scrutiny

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(CONTINUED)

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs—including any improvement in functioning—and recognizing that some types of pain cannot be completely relieved.

The Boards will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Boards consider to be within the boundaries of professional practice.

Section II: Guidelines

The Boards have adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient

> A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan

> The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(CONTINUED ON NEXT PAGE)

(+) CRITERION 3:
Opioids are part of professional practice

(+) CRITERION 6:
Prescription amount alone does not determine legitimacy

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

3. Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including

- o urine/serum medication levels screening when requested;
- o number and frequency of all prescription refills; and
- o reasons for which drug therapy may be discontinued (i.e., violation of agreement).

4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. Consultation

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

6. Medical Records

The physician should keep accurate and complete records to include

- o the medical history and physical examination;
- o diagnostic, therapeutic and laboratory results;
- o evaluations and consultations;
- o treatment objectives;
- o discussion of risks and benefits;
- o treatments;
- o medications (including date, type, dosage and quantity prescribed);
- o instructions and agreements; and
- o periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations
To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction
Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(CONTINUED ON NEXT PAGE)

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Analgesic Tolerance
Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain
A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence
Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction

Pseudoaddiction
Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

End-of-Life Care

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MCL § 333.5655

§ 333.5655. Recommended medical treatment for advanced illness; duty of physician to inform orally and in writing; requirements.

Sec. 5655. In addition to the requirements of section 5654, a physician who has diagnosed a patient as having a reduced life expectancy due to an advanced illness and is recommending medical treatment for the patient shall, both orally and in writing, inform the patient, the patient's patient surrogate, or, if the patient has designated a patient advocate and is unable to participate in medical treatment decisions, the patient advocate, of all of the following:

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(d) That the patient or the patient's surrogate or patient advocate acting on behalf of the patient may choose adequate and appropriate pain and symptom management as a basic and essential element of medical treatment.

(+) *CRITERION 2:*
Pain management is part of medical practice

MCL § 333.5658

§ 14.15(5658). Prescription of controlled substance; immunity from administrative and civil liability.

Sec. 5658. A physician who, as part of a medical treatment plan for a terminally ill patient, prescribes for the terminally ill patient a controlled substance that is included in schedules 2 to 5 under part 72 and that is a narcotic drug is immune from administrative and civil liability based on prescribing the controlled substance if the prescription is given in good faith and with the intention to treat a patient with a terminal illness or alleviate the patient's pain, or both, and all of the following are met:

(a) The prescription is for a legitimate legal and professionally recognized therapeutic purpose.

(b) Prescribing the controlled substance is within the scope of practice of the physician.

(c) The physician holds a valid license under article 7 to prescribe controlled substances.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

COMMENT: The immunity provision is valid only for physicians who prescribe for pain patients according to prognosis.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Professional Practice

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

MCL § 333.16204

§ 333.16204. Completion of courses in pain and symptom management as condition for license renewal; applicability.

Sec. 16204. (1) Effective for the renewal of licenses or registrations issued under this article and expiring after January 1, 1997 if the completion of continuing education is a condition for renewal, the appropriate board shall by rule require an applicant for renewal to complete an appropriate number of hours or courses in pain and symptom management. Rules promulgated by a board under section 16205(2) for continuing education in pain and symptom management shall cover both course length and content and shall take into consideration the recommendation for that health care profession by the interdisciplinary advisory committee created in section 16204a. A board shall submit the notice of public hearing for the rules as required under section 42 of the administrative procedures act of 1969, being *section 24.242 of the Michigan Compiled Laws*, not later than 90 days after the first interdisciplinary advisory committee makes its initial recommendations and shall promulgate the rules as expeditiously as possible.

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MCL § 333.16204a

§ 333.16204a. Advisory committee on pain and symptom management; creation; members; compensation; expenses; terms; duties; review of guidelines.

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(4) The advisory committee shall do all of the following, as necessary:

(a) At least once annually consult with all of the following boards to develop an integrated approach to understanding and applying pain and symptom management techniques:

(i) All licensure boards created under this article, except the Michigan board of veterinary medicine.

(ii) The Michigan board of social work created in section 18505 .

(b) Hold a public hearing in the same manner as provided for a public hearing held under the administrative procedures act of 1969, within 90 days after the members of the advisory committee are appointed under subsection (1) to gather information from the general public on issues pertaining to pain and symptom management.

(c) Develop and encourage the implementation of model core curricula on pain and symptom management.

(d) Develop recommendations to the licensing and registration boards and the task force created under this article on integrating pain and symptom management into the customary practice of health care professionals and identifying the role and responsibilities of the various health care professionals in pain and symptom management.

(e) Advise the licensing and registration boards created under this article on the duration and content of continuing education requirements for pain and symptom management.

(f) Annually report on the activities of the advisory committee and make recommendations on the following issues to the director of the department of consumer and industry services and to the director of the department of community health:

(i) Pain management educational curricula and continuing educational requirements of institutions providing health care education.

(ii) Information about the impact and effectiveness of previous recommendations, if any, that have been implemented, including, but not limited to, recommendations made under subdivision (d).

(iii) Activities undertaken by the advisory committee in complying with the duties imposed under subdivisions (c) and (d).

(g) Beginning in January of 2000, annually review any changes occurring in pain and symptom management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (advisory committee) to improve pain management.

STATUTES

Professional Practice

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MCL § 333.16204b

§ 333.16204b. Treatment of pain; enactment of legislation.

Sec. 16204b. The legislature finds that the treatment of pain is an appropriate issue for the legislature to consider, and that the citizens of this state would be well served by the enactment of legislation that accomplishes all of the following:

(a) Provides more and better information to health care consumers regarding the medical treatment of pain, health care coverage and benefits for the treatment of pain, and the education of health professionals in pain and symptom management.

(b) Provides for the appointment of an advisory body to study and make recommendations on model core curricula on pain and symptom management for the institutions in this state providing health care education, continuing education for health professionals on pain and symptom management, and the integration of pain and symptom management into the customary practice of health care.

(c) Educates health professionals about the disciplinary process for state licensees and registrants, including, but not limited to, how the department of consumer and industry services processes allegations of wrongdoing against licensees and registrants.

(+) *CRITERION 2:*
Pain management is part of medical practice

MCL § 333.16204c

§ 333.16204c. Medical treatment of pain; use of controlled substances; legislative findings; treatment by licensed health professionals; electronic monitoring system; "controlled substance" defined.

(+) *CRITERION 3:*
Opioids are part of professional practice

Sec. 16204c. (1) The legislature finds that the use of controlled substances is appropriate in the medical treatment of certain forms of pain, and that efforts to control diversion or improper administration of controlled substances should not interfere with the legitimate, medically recognized use of those controlled substances to relieve pain and suffering.

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(+) *CRITERION 4:*
Encourages pain management

(3) It is the intent of the legislature to permit and facilitate adequate treatment for pain by licensed health professionals, including, but not limited to, the prescription or dispensing of controlled substances included in schedule 2 under section 7214, when medically appropriate , and to enable regulatory and law enforcement agencies to prevent the abuse and diversion of controlled substances by creating an electronic monitoring system.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Professional Practice

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (information booklet) to provide practitioners information/education about pain management.

MCL § 333.16204d

§ 333.16204d. Information booklet on pain; development by department of consumer and industry services; educational program for health professionals.

Sec. 16204d. (1) The department of consumer and industry services, in consultation with the department of community health, shall develop, publish, and distribute an informational booklet on pain. The department of consumer and industry services shall include at least all of the following in the informational booklet:

(a) Pain management educational curricula and continuing educational requirements of institutions providing health care education recommended by the advisory committee on pain and symptom management under section 16204a.

(b) Other information considered relevant or useful by the department of consumer and industry services.

(2) The department of consumer and industry services, in conjunction with the controlled substances advisory commission created in article 7, shall develop and conduct an educational program for health professionals who are licensed under part 73 to prescribe or dispense, or both, controlled substances. The department of consumer and industry services shall include, at a minimum, all of the following in the educational program:

(a) Information on how the department of consumer and industry services processes allegations of wrongdoing against licensees under this article and article 17, including, but not limited to, how the permanent historical record is maintained for each licensee, how and why a review of the permanent historical record is done, and how the decision is made to issue a formal complaint against a licensee.

(b) Information on the disciplinary process, including a licensee's rights and duties if an allegation of wrongdoing is filed against the licensee or if some other circumstance occurs that causes or requires the department of consumer and industry services to review a licensee's permanent historical record.

(c) Other information considered relevant or useful by the department of consumer and industry services or the controlled substances advisory commission, especially information that would address the findings and statements of intent contained in section 16204c.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (educational program) to provide practitioners information/education about the disciplinary process regarding the treatment of pain.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Facilities and Agencies

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MCL § 333.20155

§ 333.20155. Visits to health facilities and agencies, clinical laboratories, nursing homes, hospices, and hospitals; purposes; waiver; confidentiality of accreditation information; limitation and effect; consultation engineering survey; summary of substantial noncompliance or deficiencies and hospital response; investigations or inspections; prior notice; misdemeanor; consultation visits; record; periodic reports; access to documents; confidentiality; disclosure; delegation of functions; voluntary inspections; forwarding evidence of violation to licensing agency; reports; clarification of terms; clinical process guidelines; clinical advisory committee; definitions.

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(18) Subject to subsection (19), the department, in consultation with the clarification work group appointed under subsection (16), shall develop and adopt clinical process guidelines that shall be used in applying the terms set forth in subsection (16). The department shall establish and adopt clinical process guidelines and compliance protocols with outcome measures for all of the following areas and for other topics where the department determines that clarification will benefit providers and consumers of long-term care:

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(f) Pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes mechanisms for health facilities or agencies to ensure that pain management is an essential part of patient care.

MCL § 333.20201

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§ 333.20201. Policy describing rights and responsibilities of patients or residents; adoption; posting and distribution; contents; additional requirements; discharging, harassing, retaliating, or discriminating against patient exercising protected right; exercise of rights by patient's representative; informing patient or resident of policy; designation of person to exercise rights and responsibilities; additional patients' rights; definitions.

Sec. 20201. (1) A health facility or agency that provides services directly to patients or residents and is licensed under this article shall adopt a policy describing the rights and responsibilities of patients or residents admitted to the health facility or agency. Except for a licensed health maintenance organization which shall comply with chapter 35 of the insurance code of 1956, *1956 PA 218, MCL 500.3501* to *500.3580* , the policy shall be posted at a public place in the health facility or agency and shall be provided to each member of the health facility or agency staff. Patients or residents shall be treated in accordance with the policy.

(2) The policy describing the rights and responsibilities of patients or residents required under subsection (1) shall include , as a minimum , all of the following :

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(o) A patient or resident is entitled to adequate and appropriate pain and symptom management as a basic and essential element of his or her medical treatment.

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MCL § 333.21521

§ 333.21521. Hospital to meet minimum standards and rules; protection of health and safety; preventive function.

Sec. 21521. A hospital shall meet the minimum standards and rules authorized by this article and shall endeavor to carry out practices that will further protect the public health and safety, prevent the spread of disease, alleviate pain and disability, and prevent premature death.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospitals to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospice and Hospice Residences Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospices to ensure that pain management is an essential part of patient care.

MICH. ADMIN. CODE R 325.13302

R 325.13302 Medical services.

Rule 302. (1) At the time of admission to the hospice program and its hospice residence, if applicable, and thereafter, a patient shall be under the care of a physician who shall be responsible for providing or arranging for medical care. This physician may be the attending physician.

(2) The physician providing the medical care to a patient shall be responsible for the direction and quality of medical care rendered to that patient.

(3) The physician shall review the patient's medical history and physical assessment within 48 hours before or following the patient's admission to the program.

(4) The physician shall do both of the following:

(a) Validate the prognosis and life expectancy of the patient.

(b) Assist in developing the care plan of the patient.

(5) Medical care shall emphasize prevention and control of pain and other distressing symptoms.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MN

MINNESOTA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Health; Chapter 152. Drug, Controlled Substances

- INTRACTABLE PAIN TREATMENT ACT (*Part of Controlled Substances Act*)
  Health; Chapter 152. Drug, Controlled Substances; Prescriptions; Section 125

- MEDICAL PRACTICE ACT
  Health; Chapter 147. Board of Medical Practice

- PHARMACY PRACTICE ACT
  Health; Chapter 151. Pharmacy

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Board of Pharmacy; Chapter 6800. Pharmacies and Pharmacists

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Board of Medical Practice; Chapter 5600. Licensure and Registration

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Board of Pharmacy; Chapter 6800. Pharmacies and Pharmacists

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY
  Minnesota Board of Medical Practice. *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: November 10, 2007.

- JOINT BOARD POLICY STATEMENT
  Minnesota Boards of Medical Practice, Nursing, and Pharmacy. *Joint Statement on Pain Management*. *Minnesota Board of Medical Practice Update*. Fall 2004, p. 3. Adopted: Fall, 2004.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HOSPICE LICENSING
  Health; Chapter 144A. Nursing Homes and Home Care; Hospice Care Licensing

- HOMICIDE AND SUICIDE
  Crimes, Criminals; Chapter 609. Criminal Code; Homicide and Suicide

- HOSPICE SERVICES
  Department of Health; Chapter 4664. Hospice Services

MN

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act								●
Intractable Pain Treatment Act		●	●		●			
Medical Practice Act		●						
Pharmacy Practice Act			●					
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy		●	●	●	●	●	●	●
Joint Board Policy Statement		●		●				●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Licensing								●
Homicide and Suicide								●
Hospice Services								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Intractable Pain Treatment Act		●						●
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy[1]								
Joint Board Policy Statement[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Licensing[1]								
Homicide and Suicide[1]								
Hospice Services[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

MINNESOTA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Identifies the requiring of a valid photo ID as a potential barrier to the appropriate use of opioid analgesics.

Minn. Stat. § 152.11

152.11 WRITTEN OR ORAL PRESCRIPTIONS, REQUISITES

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Subd. 2d. Identification requirement for schedule II or III controlled substance.

(a) No person may dispense a controlled substance included in schedule II or III without requiring the person purchasing the controlled substance, who need not be the person for whom the controlled substance prescription is written, to present valid photographic identification, unless the person purchasing the controlled substance, or if applicable the person for whom the controlled substance prescription is written, is known to the dispenser.

(b) This subdivision applies only to purchases of controlled substances that are not covered, in whole or in part, by a health plan company or other third-party payor. The Board of Pharmacy shall report to the legislature by July 1, 2009, on the effect of this subdivision. The board shall include in the report the incidence of complaints, if any, generated by the requirements of this subdivision and whether this subdivision is creating barriers to pharmaceutical access.

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Minn. Stat. § 152.126

152.126 SCHEDULE II AND III CONTROLLED SUBSTANCES PRESCRIPTION ELECTRONIC REPORTING SYSTEM

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Subd. 8. Evaluation and reporting.

(a) The board shall evaluate the prescription electronic reporting system to determine if the system is cost-effective and whether it is negatively impacting appropriate prescribing practices of controlled substances. The board may contract with a vendor to design and conduct the evaluation.

(b) The board shall submit the evaluation of the system to the legislature by January 15, 2010.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Identifies the prescription monitoring program as a potential barrier to the appropriate use of opioid analgesics.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 10:*
Implies opioids are not part of professional practice

(+) *CRITERION 3:*
Opioids are part of professional practice

Minn. Stat. § 152.125

152.125 Intractable pain

Subdivision 1. Definition. For purposes of this section, "intractable pain" means a pain state in which the cause of the pain cannot be removed or otherwise treated with the consent of the patient and in which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts. Reasonable efforts for relieving or curing the cause of the pain may be determined on the basis of, but are not limited to, the following:

(1) when treating a nonterminally ill patient for intractable pain, evaluation by the attending physician and one or more physicians specializing in pain medicine or the treatment of the area, system, or organ of the body perceived as the source of the pain; or

(2) when treating a terminally ill patient, evaluation by the attending physician who does so in accordance with the level of care, skill, and treatment that would be recognized by a reasonably prudent physician under similar conditions and circumstances.

Subd. 2. Prescription and administration of controlled substances for intractable pain. Notwithstanding any other provision of this chapter, a physician may prescribe or administer a controlled substance in schedules II to V of section 152.02 to an individual in the course of the physician's treatment of the individual for a diagnosed condition causing intractable pain. No physician shall be subject to disciplinary action by the board of medical practice for appropriately prescribing or administering a controlled substance in schedules II to V of section 152.02 in the course of treatment of an individual for intractable pain, provided the physician keeps accurate records of the purpose, use, prescription, and disposal of controlled substances, writes accurate prescriptions, and prescribes medications in conformance with chapter 147.

Subd. 3. Limits on applicability. This section does not apply to:

(1) a physician's treatment of an individual for chemical dependency resulting from the use of controlled substances in schedules II to V of section 152.02;

(2) the prescription or administration of controlled substances in schedules II to V of section 152.02 to an individual whom the physician knows to be using the controlled substances for nontherapeutic purposes;

(3) the prescription or administration of controlled substances in schedules II to V of section 152.02 for the purpose of terminating the life of an individual having intractable pain; or

(4) the prescription or administration of a controlled substance in schedules II to V of section 152.02 that is not a controlled substance approved by the United States Food and Drug Administration for pain relief.

Subd. 4. Notice of risks. Prior to treating an individual for intractable pain in accordance with subdivision 2, a physician shall discuss with the individual the risks associated with the controlled substances in schedules II to V of section 152.02 to be prescribed or administered in the course of the physician's treatment of an individual, and document the discussion in the individual's record.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Minn. Stat. § 147.081

147.081 Practicing without license; penalty

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Subd. 3. Practice of medicine defined. For purposes of this chapter, a person not exempted under section 147.09 is "practicing medicine" or engaged in the "practice of medicine" if the person does any of the following:

(1) advertises, holds out to the public, or represents in any manner that the person is authorized to practice medicine in this state;

(2) offers or undertakes to prescribe, give, or administer any drug or medicine for the use of another;

(3) offers or undertakes to prevent or to diagnose, correct, or treat in any manner or by any means, methods, devices, or instrumentalities, any disease, illness, pain, wound, fracture, infirmity, deformity or defect of any person;

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(+) *CRITERION 2:*
Pain management is part of medical practice

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Minn. Stat. § 151.37

151.37 Legend drugs, who may prescribe, possess

Subdivision 1. Prohibition. Except as otherwise provided in this chapter, it shall be unlawful for any person to have in possession, or to sell, give away, barter, exchange, or distribute a legend drug.

Subd. 2. Prescribing and filing. (a) A licensed practitioner in the course of professional practice only, may prescribe, administer, and dispense a legend drug, and may cause the same to be administered by a nurse, a physician assistant, or medical student or resident under the practitioner's direction and supervision, and may cause a person who is an appropriately certified, registered, or licensed health care professional to prescribe, dispense, and administer the same within the expressed legal scope of the person's practice as defined in Minnesota Statutes. A licensed practitioner may prescribe a legend drug, without reference to a specific patient, by directing a nurse, pursuant to section 148.235, subdivisions 8 and 9, physician assistant, or medical student or resident to adhere to a particular practice guideline or protocol when treating patients whose condition falls within such guideline or protocol, and when such guideline or protocol specifies the circumstances under which the legend drug is to be prescribed and administered. An individual who verbally, electronically, or otherwise transmits a written, oral, or electronic order, as an agent of a prescriber, shall not be deemed to have prescribed the legend drug. This paragraph applies to a physician assistant only if the physician assistant meets the requirements of section 147A.18.

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(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MINNESOTA BOARD OF MEDICAL PRACTICE
POLICY FOR THE USE OF CONTROLLED SUBSTANCES
FOR THE TREATMENT OF PAIN

Section I: Preamble

The Minnesota Board of Medical Practice ("Board") recognizes that principles of quality medical practice dictate that the people of the State of Minnesota have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.
Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations just as diligently as it would allegations of other misconduct relating to prescribing practices, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Board is obligated under the laws of the State of Minnesota to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) ***CRITERION 5:*** ***Addresses fear of regulatory scrutiny***

(+) ***CRITERION 6:*** ***Prescription amount alone does not determine legitimacy***

(+) ***CRITERION 8:*** ***Other provisions that may enhance pain management***

CATEGORY A: ***Issues related to healthcare professionals***

COMMENT: Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(CONTINUED)

Physicians should not fear disciplinary action from the Board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. If such prescribing meets these criteria, the Board will support physicians whose use of controlled substances has been questioned by another regulatory or enforcement agency. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for not adhering strictly to this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

1. Evaluation of the Patient
A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan
The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment
The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

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(+) ***CRITERION 3:*** ***Opioids are part of professional practice***

(+) ***CRITERION 8:*** ***Other provisions that may enhance pain treatment***

CATEGORY A: ***Issues related to healthcare professionals***

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. Periodic Review
The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

5. Consultation
The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records
The physician should keep accurate and complete records to include

- the medical history and physical examination;
- diagnostic, therapeutic and laboratory results;
- evaluations and consultations;
- treatment objectives;
- discussion of risks and benefits;
- informed consent;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- periodic reviews.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations
To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction
Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain
Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence
Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction
The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Pain management is a significant issue in health care today. Estimates of Americans experiencing pain range from 50-75 million persons annually. Thirty to fifty percent of patients undergoing cancer treatment experience pain. The effects of unmanaged pain are serious and wide-ranging and, yet, pain is widely under-treated. Untreated or inadequately treated pain impacts patients' quality of life and increases health care costs. Factors cited in the under-treatment of pain include concerns about causing addiction or tolerance; inadequate knowledge of controlled substances and pain management; fear of scrutiny and discipline by regulatory agencies; inadequate assessment; and patient reluctance to report pain or to take pain medications.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guidelines on pain management state, "Patients have the right to appropriate assessment and management of pain." (Emphasis added). It is, therefore, incumbent upon Minnesota physicians, nurses and pharmacists to work cooperatively and effectively to address the dimensions of pain and to provide maximum pain relief with minimal side effects. Towards that end, and in the interest of public protection, the Minnesota Boards of Medical Practice, Nursing and Pharmacy issue the following joint statement.

To effectively assist patients in the management of pain, health care professionals should, within their scope of practice:

- Consistently and thoroughly assess all patients for pain. If pain is reported, the pain should be evaluated with a complete history and physical with laboratory and diagnostic testing, if indicated;
- Work collaboratively in a multi-disciplinary approach to develop and implement an individualized, written treatment plan utilizing pharmacologic and non-pharmacologic interventions with specific objectives for the patient;
- Regularly evaluate the effectiveness of the treatment plan, using a consistent, developmentally appropriate, standardized pain scale, and make adjustments as needed;
- Document all aspects of pain assessment and care in a timely, clear, consistent, complete and accurate manner;
- Anticipate and effectively manage side effects of pain medications;
- Provide adequate and culturally appropriate information to patients and family members or caregivers to support patients in making informed decisions and participate in the management of their pain;
- Be aware of the risks of diversion and abuse of controlled substances and take appropriate steps to minimize these risks;
- Recognize individuals with chemical dependency may experience pain requiring medications, including opioids, and may require specialized management;
- Consult with, and refer patients to, other providers when appropriate;
- Develop organization-appropriate and evidence-based policies and protocols for pain management;
- Become and remain knowledgeable regarding effective pain management; and
- Comply with all state and federal laws and regulations regarding prescribing, dispensing, and administering legend drugs, including controlled substances.

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(+) *CRITERION 4:*
Pain management is encouraged

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes a practitioner's responsibility to provide patients information about pain management and palliative care when considering treatment options.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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Resources:

American Pain Foundation
201 North Charles Street, Suite 710
Baltimore, MD 21201-4111
1-888-615-PAIN (7246)
http://www.painfoundation.org/

American Pain Society
http://www.ampainsoc.org/

DEA
http://www.deadiversion.pdf/

Federation of State Medical Boards: Model Policy for use of Controlled Substances for the Treatment of Pain.
http://www.fsmb.org/

"Guideline for Pain Management." Kansas State Board of Nursing (2001).

"Joint Statement on Pain Management in End-of-Life Care." North Carolina Boards of Nursing, Pharmacy and Medicine (1999).

"MNA Position Statement: Pain Management." Minnesota Nurses Association, (2000).

http://www.painandhealth.org/

"Pain Management Policy." California Board of Registered Nursing. (1999)

"Position Statement on Pain Management and Control of Distressing Symptoms in Dying Patients." American Nurses Association. (2003).

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MINNESOTA

STATUTES

Hospice Licensing

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Minn. Stat. § 144A.751

144A.751 Hospice bill of rights

Subdivision 1. Statement of rights. An individual who receives hospice care has the right to:

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(22) have pain and symptoms managed to the patient's desired level of comfort.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospices to ensure that pain management is an essential part of patient care.

STATUTES

Homicide and Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Minn. Stat. § 609.215

609.215 Suicide

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Subd. 3. Acts or omissions not considered aiding suicide or aiding attempted suicide. (a) A health care provider, as defined in section 145B.02, subdivision 6, who administers, prescribes, or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, does not violate this section unless the medications or procedures are knowingly administered, prescribed, or dispensed to cause death.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospice Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

Minn. R. 4664.0100

4664.0100 ASSESSMENT

Subpart 1. Requirement. A hospice provider must ensure that each hospice patient and hospice patient family has a current assessment. An interdisciplinary team must complete an individualized, comprehensive assessment of each hospice patient and hospice patient family's needs. The assessment must address, but is not limited to, the physical, nutritional, emotional, social, spiritual, pain, symptom management, medication, and special needs of the hospice patient and hospice patient's family during the final stages of illness, dying, and bereavement, and any other areas necessary to the provision of hospice care.

Subp. 2. Fines. A fine of $ 350 shall be assessed for each violation of this part.

Minn. R. 4664.0330

4664.0330 INPATIENT CARE

Subpart 1. Short-term inpatient care. A hospice provider must ensure that inpatient care is available for pain control, symptom management, and respite purposes and is provided in a licensed hospital, a nursing home, or a residential hospice facility. Inpatient care must be provided directly or under arrangement with one or more hospitals, nursing homes, or residential hospice facilities.

Subp. 2. Fines. A fine of $ 300 shall be assessed for each violation of this part.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospices to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MS

MISSISSIPPI

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 41. Public Health; Chapter 29. Poisons, Drugs and Other Controlled Substances; Article 3. Uniform Controlled Substances Law

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 73. Professions and Vocations; Chapter 25. Physicians

- PHARMACY PRACTICE ACT
  Title 73. Professions and Vocations; Chapter 21. Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Agency 50. Regulatory Agencies; Sub-Agency 018. Pharmacy Board

- MEDICAL BOARD REGULATIONS
  Agency 50. Regulatory Agencies; Sub-Agency 013. Board of Medical Licensure

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Agency 50. Regulatory Agencies; Sub-Agency 018. Pharmacy Board

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  Mississippi State Board of Medical Licensure. *Pain, Pain Management and Mississippi State Board of Medical Licensure Scrutiny*. *MSBML Newsletter*. Vol. 1, No. 10. Fall 1997.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HOSPICE STANDARDS
  Agency 12. Department of Health; Sub-Agency 000. General; Chapter 039. Minimum Standards of Operation for Hospice

- HOSPITAL STANDARDS
  Agency 12. Department of Health; Sub-Agency 000. General; Chapter 040. Minimum Standards of Operation for Hospitals

MS

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Pharmacy Practice Act			●					●
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board		●	●				●	●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement		●		●				●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Standards								●
Hospital Standards								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board		●		●			●	●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement	●							
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Standards[1]								
Hospital Standards[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

MISSISSIPPI

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Miss. Code Ann. § 41-29-105

§ 41-29-105. Definitions

The following words and phrases, as used in this article, shall have the following meanings, unless the context otherwise requires:

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(y) "Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator, optometrist certified to prescribe and use therapeutic pharmaceutical agents under Sections 73-19-153 through 73-19-165, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state; and

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(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Miss. Code Ann. § 73-21-83

§ 73-21-83. Board to regulate practice of pharmacy; licensing of pharmacists; fees; persons holding license on July 1, 1991

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(2) A license for the practice of pharmacy shall be obtained by all persons prior to their engaging in the practice of pharmacy. However, the provisions of this chapter shall not apply to physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of the State of Mississippi and are authorized to dispense and administer prescription drugs in the course of professional practice.

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Miss. Code Ann. § 73-21-127

§ 73-21-127. Board of Pharmacy to develop and implement computerized program to track certain prescriptions; report of illegal activity; confidentiality of information obtained from program

The Board of Pharmacy shall develop and implement a computerized program to track prescriptions for controlled substances and to report illegal activity, under the following conditions:

(a) The prescriptions tracked shall be prescriptions for controlled substances listed in Schedule II, III, IV or V that are filled by a pharmacy. The program shall provide information regarding the inappropriate use of controlled substances in Schedule II, III, IV and V to pharmacies, practitioners and appropriate state agencies in order to prevent the improper or illegal use of such controlled substances. The program shall not infringe on the legal use of controlled substances for the management of severe or intractable pain.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulation

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

CMSR 50-013-001

50 013 001. Article XXIII. Regulations Pertaining to Prescribing, Administration and Dispensing of Medication

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F. USE OF CONTROLLED SUBSTANCES FOR CHRONIC (Non-Terminal) PAIN:

1. DEFINITIONS:
For the purpose of Article F only, the following terms have the meanings indicated:

a. "Chronic Pain" is a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and one or more physicians specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain. Further, if a patient is receiving controlled substances for the treatment of pain for a prolonged period of time (more than six months), then they will be considered for the purposes of this regulation to have "de facto" chronic pain and subject to the same requirements of this regulation. "Terminal Disease Pain" should not be confused with "Chronic Pain." For the purpose of this Section, "Terminal Disease Pain" is pain arising from a medical condition for which there is no possible cure and the patient is expected to live no more than six (6) months.

b. "Acute Pain" is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time limited and is responsive to therapies, including controlled substances as defined by the U.S. Drug Enforcement Administration. Title 21 CFR Part 1301 Food and Drugs.

c. "Addiction" is a neurobehavorial syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

d. "Physical Dependence" is a physiological state of neuroadaptation to a substance which is characterized by the emergence of a withdrawal syndrome if the use of the substance is stopped or decreased abruptly, or if an antagonist is administered. Withdrawal may be relieved by re-administration of the substance. Physical dependence is a normal physiological consequence of extended opioid therapy for pain and should not be considered addiction.

e. "Substance Abuse" is the use of any substance(s) for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.

f. "Tolerance" is a physiological state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose. Tolerance occurs to different degrees for various drug effects, including sedation, analgesia and constipation. Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Such tolerance may or may not be evident during treatment and does not equate with addiction,

2. Notwithstanding any other provisions of these rules and regulations, a physician may prescribe, administer, or dispense controlled substances in Schedules II, IIN, III, IIIN, IV and V, or other drugs having addiction-forming and addiction-sustaining liability to a person in the usual course of treatment of that person for a diagnosed condition causing chronic pain.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Does this imply that opioids are a treatment of last resort?

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 2:*
Pain management is part of medical practice

(-) *CRITERION 10:*
Implies opioids are not part of professional practice

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY B:
Mandated consultation

(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulation

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

a. Before initiating treatment utilizing a Schedules II, IIN, III, IIIN, IV or V controlled substance, or any other drug having addiction-forming and addiction-sustaining liability, the physician shall conduct an appropriate risk/benefit analysis by reviewing his own records of prior treatment, or review the records of prior treatment which another treating physician has provided to the physician, that there is an indicated need for long term controlled substance therapy. Such a determination shall take into account the specifics of each patients diagnosis, past treatments and suitability for long term controlled substance use either alone or in combination with other indicated modalities for the treatment of chronic pain. This shall be clearly entered into the patient medical record, and shall include consultation/referral reports to determine the underlying pathology or cause of the chronic pain.

b. Documentation in the patient record shall include a complete medical history and physical examination that indicates the presence of one or more recognized medical indications for the use of controlled substances.

c. Documentation of a written treatment plan which shall contain stated objectives as a measure of successful treatment and planned diagnostic evaluations, e.g., psychiatric evaluation or other treatments. The plan should also contain an informed consent agreement for treatment that details relative risks and benefits of the treatment course. This should also include specific requirements of the patient, such as using one physician and pharmacy if possible, and urine/serum medication level monitoring when requested.

d. Periodic review and documentation of the treatment course is conducted at reasonable intervals (no more than every six months) with modification of therapy dependent on the physician's evaluation of progress toward the stated treatment objectives. This should include referrals and consultations as necessary to achieve those objectives.

4. No physician shall administer, dispense or prescribe a controlled substance or other drug having addiction-forming and addiction-sustaining liability that is nontherapeutic in nature or non-therapeutic in the manner the controlled substance or other drug is administered, dispensed or prescribed.

5. No physician shall administer, dispense or prescribe a controlled substance for treatment of chronic pain to any patient who has consumed or disposed of any controlled substance or other drug having addiction-forming and addiction-sustaining liability other than in strict compliance with the treating physician's directions. These circumstances include those patients obtaining controlled substances or other abusable drugs from more than one physician and those patients who have obtained or attempted to obtain new prescriptions for controlled substances or other abusable drugs before a prior prescription should have been consumed according to the treating physician's directions. This requirement will not be enforced in cases where a patient has legitimately temporarily escalated a dose of their pain medication due to an acute exacerbation of their condition but have maintained a therapeutic dose level, however it will be required of the treating physician to document in the patient record that such increase in dose level was due to a recognized indication and was within appropriate therapeutic dose ranges. Repetitive or continuing escalations should be a reason for concern and a re-evaluation of the present treatment plan shall be undertaken by the physician.

6. No physician shall prescribe any controlled substance or other drug having addiction-forming or addiction-sustaining liability to a patient who is a drug addict for the purpose of "detoxification treatment", or "maintenance treatment", and no physician shall administer or dispense any narcotic controlled substance for the purpose of "detoxification treatment" or "maintenance treatment" unless they are properly registered in accordance with Section 303(g) *21 U.S.C. 823*(g). Nothing in this paragraph shall prohibit a physician from administering narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one (1) day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three (3) days. Nothing in this paragraph shall prohibit a physician from administering or dispensing narcotic controlled substances in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction.

(-) *CRITERION 15:*
Other provisions that may impede pain management

COMMENT: Fails to recognize that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exemption of these patients from special prescription requirements nevertheless continues those requirements for all other patients.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

PAIN, PAIN MANAGEMENT AND MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE SCRUTINY

The skillful management of pain is one of the most valuable services a physician can provide. This service calls into play many components of the art and science of medicine and the technological skills that physicians possess. The result of pain management, skillfully done, is most rewarding to the patient and physician alike.

In many respects, the mechanism of pain is a mystery, but it is a mystery that is being progressively untangled. There have been many advances in our knowledge, allowing a better understanding of pain mechanisms and the therapeutic approaches to pain. We now know that:

Pain may be perceived peripherally, at several levels in the spinal cord and mid brain, and in the central nervous system. This knowledge allows pain to be classified and to be treated in different ways, depending on the level where it is perceived.

There are natural-endogenous agonist and antagonist influences and some knowledge of how these can be brought into play.

There are many factors which influence pain, i.e.:

a. The patient's general situation with his family, employment, finances, spirituality, marital status, et al.;

b. The patient's previous responses to pain and to pain medications;

c. The patient's disease, whether it is due to an acute problem where healing and return to normal is expected, a terminal problem where progression of the disease to death within an estimated six (6) months or less, or a chronic non-terminal source of the pain where neither of the outcomes stated above is expected; and

d. The patient's attitude toward the pain.

Pain therapy is multimodal and with the above knowledge, a plan of therapy can be selectively evolved that is effective in most cases. A general recitation of these modes is as follows:

a. Behavior modification-psychological evaluation and intervention;

b. Physical therapy ranging from therapeutic exercises and joint manipulation to a variety of modalities including hydrotherapy, thermotherapy, manipulation to change threshold of sensory nerve ends (TENS), and others;

c. Analgesics to include NSAIDS, antidepressants and anticonvulsants;

d. Where indicated, a variety of maneuvers ranging from nerve blocks to ablative surgery; and

e. Controlled substances, including drugs for anxiety and depression, as well as opioids of appropriate strength.

With a working knowledge of all these things, the physician, using good clinical judgement, can create and carry out a plan that will satisfactorily resolve most pain problems and minimize the side effects and potential side effects of all these modes of therapy.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

Many physicians are astute in the management of acute pain associated with surgery, trauma, and procedures. A growing number of physicians are becoming adept in the management of the pain of terminal disease. These terminal diseases include a number of cancers, AIDS, a number of progressive neurological diseases, end-stage heart and lung disease, and a variety of other disorders.

Adequate relief of acute pain requires regular doses of an ample amount of medication, as well as supportive measures with physical therapy therapeutic exercises, i.e., walking and breathing exercises, et al. Here the physiologic injury is soon repaired, and the patient returns to normal.

Palliative terminal care requires much supportive treatment involving psychosocial, pastoral care, physical therapy, family therapy, and a degree of occupational therapy. Compassionate care on the part of all care givers to the patients and their families is a must. Medication must be managed skillfully to assure that increasing amounts are appropriate. Therapy and medication are required for the wide variety of problems that inevitably arise with these situations. The ability to help patients to die graciously and in comfort has traditionally been an outstanding asset of physicians who care for these patients.

(+) *CRITERION 4:*
Encourages pain management

The Mississippi State Board of Medical Licensure supports the adequate treatment of all pain. In the acute and terminal categories of pain, the Board's concern is that they not be under treated.

Chronic pain of the non-terminal disorders is where problems arise. It is here that skills in pain management are stretched to the limit. All of the skills embodied in the art and science of medicine and the technologies involved in pain management are called into play.

Successful management in the case of chronic non-terminal pain requires:

Patient evaluation skills to provide a diagnosis and mechanism for the pain.

Management skills in evolving a plan of therapy that brings all the multimodal elements of the therapeutic armamentarium under consideration and selects out those that are most appropriate in each particular case.

Self-evaluation skills to know what you know, and to know what you do not know, and to know when consultation may be sought with pain specialists, addictionologists, orthopedic surgeons, neurologists, neurosurgeons and others who can provide help in establishing a diagnosis and a mechanism for the pain, and can help evolve an appropriate plan of therapy.

Appropriate and timely monitoring of all modes of therapy including medications.

Awareness of and a watchful eye for the possibility of drug dependency and/or addiction where controlled substances are used.

Documentation of all evaluations, the plan of therapy, observations made on follow-up visits (especially the response to therapy and the continuing need for therapy, including everything but especially with regard to controlled drug use). Remember, if it is not documented, who is to say that it happened.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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What Does the Licensure Board Require of You?

I. The Mississippi State Board of Medical Licensure publishes a book entitled *LAWS, RULES AND REGULATIONS GOVERNING THE PRACTICE OF PHYSICIANS (M.D./D.O.) AND PODIATRIST (D.P.M.).* Section 2 of this publication is entitled "RULES PERTAINING TO PRESCRIBING, ADMINISTRATION AND DISPENSING OF MEDICATION." We strongly suggest you familiarize yourself with these rules and regulations based on the law.

Follow all of the steps described in the section on the successful management of non-terminal chronic pain.

Know that a medical record documenting all things is not only part of good patient management, but allows any outside agency (such as the Mississippi State Board of Medical Licensure) that may examine these records to have good insight into what was done, medications prescribed, dosage of medications, how often medication is given, and time period medication is prescribed.

Know that the Board will have no quarrel with you if:

(a) an appropriate good faith history and physical, along with other appropriate studies to make a diagnosis and to understand so far as is possible the mechanism of the pain;

(b) a plan of therapy is evolved and utilized using all the available modes of therapy available and appropriate for each particular patient;

(c) appropriate consultation is obtained;

(d) controlled substances are used only after all other measures and non-controlled analgesics are found to be ineffective; and

(e) all of this is timely and appropriately documented.

(-) *CRITERION 9:*
Opioids are a last resort

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospice Standards

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (medical director's responsibility) for hospices to ensure that pain management is an essential part of patient care.

CMSR 12-000-039

12 000 039. Minimum Standards of Operation for Hospice

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PART IV ADMINISTRATION

400

Section A. Administration.

400.1. Governing Body - A hospice shall have a governing body that assumes full legal responsibility for compliance with these regulations and for setting policy, appointing persons to carry out such policies, and monitoring the hospice's total operation.

400.2. Medical Director -

(a) Each hospice shall have a medical director, who, on the basis of training, experience and interest, shall be knowledgeable about the psychosocial and medical aspects of hospice care.

(b) The medical director shall be appointed by the governing body or its designee.

(c) The duties of the medical director shall include, but not be limited to:

1. Consultation with attending physicians, as requested, regarding pain and symptom management;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospital Standards

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (policies and procedures) for hospitals to ensure that pain management is an essential part of patient care.

CMSR 12-000-040

12 000 040. Minimum Standards of Operation for Hospitals
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803

Written nursing care and administrative policies and procedures shall be developed to provide the nursing staff with acceptable methods of meeting its responsibilities and achieving projected goals through realistic and attainable goals.
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803.2
Policies shall be developed to address the following:
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K. Pain Management.

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805.1

All nursing personnel shall have training and a program of in-service and continuing education commensurate with the duties and responsibilities of the individual. All training shall be documented for each individual so employed.

The in-service should include but not limit topics to pressure sore prevention, prevention of medication errors, pain management, patient's rights and dignity.
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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (training) for hospitals to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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MISSOURI

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 12. Public Health and Welfare; Chapter 195. Drug Regulations; Narcotic Drug Act

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 22. Occupations and Professions; Chapter 334. Physicians and Surgeons, Therapists, Athletic Trainers, Health Care Providers

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Title 22. Occupations and Professions; Chapter 334. Physicians and Surgeons, Therapists, Athletic Trainers, Health Care Providers; Sections 334.105-334.107

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 22. Occupations and Professions; Chapter 338. Pharmacists and Pharmacies

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 19. Department of Health and Senior Services; Division 30. Division of Regulation and Licensure; Chapter 1. Controlled Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 20. Department of Insurance, Financial Institutions and Professional Registration; Division 2150. State Board of Registration for the Healing Arts; Chapter 2. Licensing of Physicians and Surgeons

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 20. Department of Insurance, Financial Institutions and Professional Registration; Division 2220. State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Missouri State Board of Healing Arts. *Missouri Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted: 2007

- MEDICAL BOARD GUIDELINE
  Missouri State Board of Registration for the Healing Arts. *Palliative Care Guidelines*. Adopted: January, 2001.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- ADVISORY COUNCIL ON PAIN AND SYMPTOM MANAGEMENT
  Title 12. Public Health and Welfare; Chapter 192. Department of Health; Missouri State Advisory Council on Pain and Symptom Management

- HOSPICE SERVICES PROGRAM
  Title 13. Department of Social Services; Division 70. Division of Medical Services; Chapter 50. Hospice Services Program

- HOSPICE PROGRAM OPERATIONS
  Title 19. Department of Health and Senior Services; Division 30. Division of Regulation and Licensure; Chapter 35. Hospices

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Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Intractable Pain Treatment Act		●	●		●			●
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances			●					
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
Medical Board Guideline				●				●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Advisory Council on Pain and Symptom Management								●
Hospice Services Program								●
Hospice Program Operations								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

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Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Intractable Pain Treatment Act		●		●				●
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
Medical Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Advisory Council on Pain and Symptom Management[1]								
Hospice Services Program[1]								
Hospice Program Operations[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

§ 195.010 R.S.Mo.

§ 195.010. Definitions

The following words and phrases as used in sections 195.005 to 195.425, unless the context otherwise requires, mean:

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(15) "Drug dependent person", a person who is using a controlled substance and who is in a state of psychic or physical dependence, or both, arising from the use of such substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence;

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(35) "Practitioner", a physician, dentist, optometrist, podiatrist, veterinarian, scientific investigator, pharmacy, hospital or other person licensed, registered or otherwise permitted by this state to distribute, dispense, conduct research with respect to or administer or to use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in this state, or a pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research;

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

§ 334.105 R.S.Mo. – § 334.106 R.S.Mo.

§ 334.105. Intractable pain treatment act--definitions

1. *Sections 334.105* to *334.107* shall be known and may be cited as the "Intractable Pain Treatment Act".

2. For purposes of *sections 334.105* to *334.107*, the following terms mean:

(1) "Board", the state board of registration for the healing arts;

(2) "Intractable pain", a pain state in which the cause of pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts that have been documented in the physician's medical records;

(3) "Physician", physicians and surgeons licensed pursuant to this chapter by the board;

(4) "Therapeutic purpose", the use of controlled substances in acceptable doses with appropriate indication for the treatment of pain. Any other use is nontherapeutic.

§ 334.106. Intractable pain treatment physician may prescribe controlled substances for therapeutic purposes, requirements--exceptions

1. Notwithstanding any other provision of law to the contrary, a physician may prescribe, administer or dispense controlled substances for a therapeutic purpose to a person diagnosed and treated by a physician for a condition resulting in intractable pain, if such diagnosis and treatment has been documented in the physician's medical records. No physician shall be subject to disciplinary action by the board solely for prescribing, administering or dispensing controlled substances when prescribed, administered or dispensed for a therapeutic purpose for a person diagnosed and treated by a physician for a condition resulting in intractable pain, if such diagnosis and treatment has been documented in the physician's medical records.

2. The provisions of subsection 1 of this section shall not apply to those persons being treated by a physician for chemical dependency because of their use of controlled substances not related to the therapeutic purposes of treatment of intractable pain.

3. The provisions of subsection 1 of this section provide no authority to a physician to prescribe, administer or dispense controlled substances to a person the physician knows or should know to be using controlled substances which use is not related to the therapeutic purpose.

4. Drug dependency or the possibility of drug dependency in and of itself is not a reason to withhold or prohibit the prescribing, administering or dispensing of controlled substances for the therapeutic purpose of treatment of a person for intractable pain, nor shall dependency relating solely to such prescribing, administering or dispensing subject a physician to disciplinary action by the board.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(-) *CRITERION 10:*
Implies opioids are not part of professional practice

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: "Acceptable doses" implies there is a limit, but the limit is not specified and who determines the limit?

(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY C:
Conflicting or inconsistent policies or provisions

COMMENT: Appears to be inconsistency between these provisions relating to the use of opioids for a person with pain who is drug dependent.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3: Opioids are part of professional practice*

19 CSR 30-1.011

30-1.011 Definitions

(1) As used in this chapter, the following terms shall have the meanings specified:

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(F) Individual practitioner means a physician, dentist, veterinarian, optometrist or other individual licensed, registered or otherwise permitted by the United States or Missouri to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy or an institutional practitioner;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Missouri Guidelines for the Use of Controlled Substances for the Treatment of Pain

Effective January 2007, the Board of Healing Arts appointed a Task Force to review the current statutes, rules and guidelines regarding the treatment of pain. This Task Force consisted of both staff and Board members, with input from the Governor's Council on Pain and Symptom Management. They were charged with gathering information and to draft language for the Board to review.

In the report, the committee members made recommendations that included:

- √ Developing a pain and symptom management website for healthcare professionals and the general public.
- √ Encouraging hospitals to increase their medical and nursing staff's knowledge by providing guidelines for required curricula in pain and symptom management in their educational programs.
- √ Encouraging pharmacies within communities or among pharmacy chains to share information and stock adequate supplies of Schedule II medications to meet the needs of patients.
- √ Evaluating patients with complete history and physicals and adding previous pain physician(s) records with their current medical records.
- √ Documenting any pain agreements between the patients and the physician and add this along with an informed consent to the medical records.
- √ Making appropriate referrals.

The Missouri Guidelines are not intended to define complete or best practice but rather to communicate what the Board considers to be within the boundaries of professional practice. The guidelines state that patients should have access to appropriate and effective pain relief that will serve to improve the quality of life for those who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain.

The Missouri guidelines have been broken down into the following sections:

- Section I: Preamble
- Section II: Guidelines (Evaluation of the Patient: Treatment Plan; Informed Consent and Agreement for Treatment; Periodic Review; Consultation; Medical Records; Compliance with Controlled Substances Laws and Regulations)
- Section III: Definitions (Acute Pain; Addiction; Analgesic Tolerance; Chronic Pain; Pain; Physical Dependence; Pseudoaddiction; Substance Abuse; Tolerance)

To view and/or print a complete copy of the Missouri guidelines, please go to our website at www.pr.mo.gov/healingarts.asp

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

The Missouri Guidelines for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Missouri Board of Healing Arts recognizes that the people of the State of Missouri have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

These guidelines have been developed to clarify the Boards' position on pain control, to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the U.S. Food and Drug Administration Consumer Magazine the March/April 2004 Issue Publication number FDA04-1336C entitled "Managing Chronic Pain", for a sound approach to the management of chronic pain. The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and nonpharmacologic modalities. During the treatment of pain the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics are not synonymous with addiction.

The Board is obligated under the laws of the State of Missouri to protect the public health and safety. The Board recognizes that prescribing of controlled substances, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be aware of the methods for preventing the diversion of drugs for illegitimate purposes.

Physicians should not fear disciplinary action from the Board or other state regulatory enforcement agencies for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and based on sound clinical grounds. Sound clinical grounds include a working diagnosis for the etiology of the pain. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be accompanied by clear documentation in the medical record of the treatment and in compliance with applicable state or federal law with the Board of Healing Arts § 334 RSMo; §334.105 RSMo; and §195 RSMo and with the Bureau of Narcotic and Dangerous Drugs and the Drug Enforcement Agency §21 USC.

Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs—including any improvement in functioning—and recognizing that some types of pain cannot be completely relieved. The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within boundaries of professional practice.

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(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient
A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of controlled substances.

2. Treatment Plan
The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment
The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (i.e., violation of agreement).

4. Periodic Review
At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. Consultation
The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

[CONTINUED ON NEXT PAGE]

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

6. Medical Records
The physician should keep accurate records including complete medical history and physical examination;

- diagnostic, therapeutic and laboratory results;
- evaluations and consultations;
- treatment objectives;
- discussion of risks and benefits;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations
To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations. The Physician's Manual can be found at the DEA Diversion website at www.deadiversion.usdoj.gov . The State guidelines can be found under Chapter 195.070 RSMo and 334.105 RSMo.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction
Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Analgesic Tolerance
Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain
A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Pseudoaddiction
Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Missouri State Board of Registration for the Healing Arts
Palliative Care Guidelines

During recent meetings, the Missouri Board of Healing Arts has held several discussions regarding the treatment of terminally ill patients and their concern that physicians who are treating these patients are not knowledgeable about palliative care. It is the Board's position that physicians who care for terminally ill patients should be knowledgeable about palliative care. The Board's definition of palliative care includes, fully assessing and evaluating the patient's needs; understanding the patient's goals and values; helping with advance care planning and honestly discussing treatment options; aggressively managing pain and other symptoms; using the team approach; and documenting the case. If you are treating terminally ill patients, you are encouraged to follow the following guidelines:

A) Evaluating the Patient:
A patient with life limiting chronic illness should be given the option of palliative care. Physicians should use prognostic guidelines to identify patients who are entering the terminal period of their lives. Assessment should include the patient's disease state, prognosis, physical symptoms, and psychosocial and spiritual concerns. Coexisting disease and the impact of symptoms on functioning should be documented. The needs of the family, or other caregivers, for information and support should be assessed.

B) Understanding the Patient's Goals and Values:
Discussions between the patient and physician about advanced directives and goals and values of the patient are central to palliative care and should be conducted as early as possible in the clinical course to maximize patient input to decision-making. It is advisable to have the patient name which person, or persons should serve as substitute decision-maker if the patient is no longer able to participate in decision-making. The patient's preferences should be documented in an advance directive. The substitute decision-maker should follow the patient's expressed wishes.

C) Discussing Treatment Options:
The burdens and benefits of shifting from curative treatment to palliative care need to be carefully explained by the physician to the decisional patient or substitute decision-maker to obtain informed consent for the care plan. This plan should be based on the goals of the decisional patient or those expressed in the patient's advance directive. The consensus of the family should also be sought. Decisions about resuscitation and withholding and withdrawing treatment should be consistent with these goals.

D) Aggressive Management of Pain and Symptoms:
It is the ethical responsibility of the physician to provide pain and symptom management that promotes the best quality of life for the patient. Physical symptoms may not be controlled by standard treatment when the patient has unrelieved emotional or spiritual suffering. Multidisciplinary assessment and treatment should be used to define and address the many dimensions of suffering. Refer to the Missouri Intractable Pain Treatment Act for guidelines in pain management. (Missouri Statutes 334.105, 334.106, 334.107)

E) Team Approach:
The multiple types of suffering experienced by patients and families may best be managed by a team approach: an effective multidisciplinary team of professionals as indicated by the patient's needs with interest and expertise in palliative care. Examples of such teams are a hospice program, an informal group of skilled professionals, or a palliative care consultation team.

F) Documentation:
Good documentation protects patient preferences. All discussions and treatment decisions should be documented by the physician in the medical record. Such documentation should be accessible for guiding subsequent decisions. To evaluate effectiveness of treatment, documentation of pain assessment and treatment response should use a standard pain scale when possible.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Advisory Council on Pain and Symptom Management

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (advisory council) to improve pain management.

§ 192.350 R.S.Mo.

§ 192.350. Pain and symptom management advisory council created, appointment, qualifications, terms, vacancies, how filled

1. There is hereby established within the department of health and senior services the "Missouri State Advisory Council on Pain and Symptom Management". The council shall consist of nineteen members that are residents of this state. The members of the council shall include:

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REGULATIONS

Hospice Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (inpatient care) for hospices to ensure that pain management is an essential part of patient care.

13 CSR 70-50.010

70-50.010 Hospice Services Program

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The following services are hospice-covered services when specified in the individual's plan of care:

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(I) Short-term inpatient care required for procedures necessary for pain control or acute or chronic symptom management provided in a participating hospice inpatient unit, or a participating hospital, or nursing facility (NF) that additionally meets the special hospice standards regarding staffing and patient areas;

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19 CSR 30-35.010

30-35.010 Hospice Program Operations

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(G) Clinical Services. The hospice shall routinely provide through direct employees the following services:

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2. Medical director services. The medical director shall be a direct or contract employee. The medical director's or designee's services and responsibilities include:

A. Consulting with attending physicians regarding pain and symptom control;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (medical director services) for hospices to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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MONTANA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 50. Health and Safety; Chapter 32. Controlled Substances

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 37. Professions and Occupations; Chapter 3. Medicine

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 37. Professions and Occupations; Chapter 7. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Title 24. Department of Labor and Industry; Chapter 174. Pharmacy; Sub-Chapter 14. Dangerous Drug Act

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 24. Department of Labor and Industry; Chapter 156. Medical Examiners

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 24. Department of Labor and Industry; Chapter 174. Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Montana Board of Medical Examiners. *Statement on the Use of Controlled Substances in the Treatment of Intractable Pain*. *Montana Medical Association Bulletin*. Vol. 51, pp. 3-4. June 1996. Adopted: March 15, 1996.

- JOINT BOARD POLICY STATEMENT
  Montana Board of Medical Examiners, Board of Nursing, and Board of Pharmacy. *Statement of the Prescribing and Filling of Controlled Substances in the Treatment of Chronic Pain*. Adopted: July 27, 2002.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

No policies found

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline				●	●			●
Joint Board Policy Statement			●	●				●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES[2]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline	●			●				
Joint Board Policy Statement	●							
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES[2]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

MONTANA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

Mont. Code Anno., § 50-32-101

50-32-101 Definitions.

As used in this chapter, the following definitions apply:

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(23) "Practitioner" means:

(a) a physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, or conduct research with respect to or to administer a dangerous drug in the course of professional practice or research in this state;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MONTANA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

STATEMENT ON THE USE OF CONTROLLED
SUBSTANCES IN THE TREATMENT OF INTRACTABLE PAIN

The Montana Board of Medical Examiners continues to be concerned about the use of controlled substances by individuals who seek them for their mood-altering and addictive potential rather than legitimate medical reasons. However, the Board is also concerned about adequate pain management. The Board recognizes that pain from whatever cause is often under treated. The Board is aware that there are a number of factors that continue to interfere with effective pain management. These include exaggerated fears of opioid side effects including addiction, fear of legal consequences when controlled substances are used, low priority of proper pain management in our health care system, and the lack of integration of current knowledge concerning pain management into medical education and clinical practice.

The Board seeks to assure that no Montanan requiring narcotics for pain relief is denied them because of a physician's real or perceived fear that the Board of Medical Examiners will take disciplinary action based solely on the use of narcotics to relieve pain. While improper use of narcotics, like any improper medical care, will continue to be a concern of the Board, the Board is aware that treatment of malignant and especially nonmalignant pain is a very difficult task. The Board does not want to be a hindrance to the proper use of opioid analgesics. Treatment of chronic pain is multifactorial and certainly treatment with modalities other than opioid analgesics should be utilized, usually before long term opioids are prescribed. Use of new or alternative types of treatment should always be considered for intractable pain periodically, in attempts to either cease opioid medications or reduce their use.

The proper use of opioid analgesics for chronic pain must involve certain elements, which are also consistent with any quality medical care. The following guidelines will help assure the proper use of these medications for chronic pain and minimize the improper use:

GUIDELINES FOR PRESCRIBING OPIOID ANALGESICS FOR CHRONIC PAIN

1. Thorough history and physical examination. Included in the history is assessment of the etiology of pain, physical and psychological function of the patient, substance abuse history, other treatments that have been attempted to control the patient's level of pain, identification of underlying or coexisting diseases or conditions and, as much as possible, statements by all treating physicians that the patient's pain is intractable and not controlled by other than the use of opioid analgesics.

2. Treatment plan. A thoroughly documented, written treatment plan should be established and should include how treatment success will be evaluated, such as pain relief and improved physical or psychological functioning. Several treatment modalities should be utilized in most cases and should be done concurrently with the use of opiates. Periodic review by the physician should be accomplished to determine that there are no other appropriate treatment methods that would then be of additional benefit to the patient.

3. Informed consent. The physician should discuss the risks and benefits of the use of controlled substances with the patient and/or guardian and this should be accomplished on an ongoing basis, not just at the initiation of treatment.

4. Appropriate referral. If treatment objectives are not being realized or if patients appear to be at risk for misuse of medications, referral should be made to appropriate specialists including addiction specialists and chronic pain specialists.

5. Documentation. All the above recommendations and guidelines should be recorded accurately and completely in the patient's medical record.

We hope that the above statements and guidelines will help reverse the trend of under treatment of intractable pain, and that they will facilitate the more appropriate use of controlled substances by duly licensed practitioners with prescriptive authority in the State of Montana.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(-) *CRITERION 9:*
Opioids are a last resort

(-) *CRITERION 12:*
Medical decisions are restricted

***CATEGORY D*:**
Undue prescription limitations

COMMENT: "Drug holidays" are no longer recognized as appropriate medical practice.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that efforts to reduce the abuse and diversion of controlled substances should not interfere with legitimate medical use.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goals of pain treatment should extend beyond pain scores, to include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

MONTANA

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies an important barrier to the appropriate use of opioid analgesics; however, addiction-related terms (this concept is referred to as "pseudoaddiction") are clearly defined in the Federation's model medical board policies, which Montana has not yet adopted.

(-) *CRITERION 9:*
Opioids are a last resort

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

STATEMENT OF THE PRESCRIBING AND FILLING OF CONTROLLED SUBSTANCES IN THE TREATMENT OF CHRONIC PAIN

The Montana Board of Medical Examiners, Montana Board of Nursing and Montana Board of Pharmacy recognize that pain has historically been under treated due to an exaggerated fear of patient addiction and diversion of pain medication with corresponding fear of legal consequences and a lack of current knowledge concerning pain management. Untreated chronic pain can lead to clinical exacerbations, increased suffering and eventual disability. Patient requests for more pain medication can often be interpreted as drug seeking behavior, when inadequately treated pain is actually the cause.

Improper prescribing and dispensing of opioids will continue to be a concern of the Montana Board of Medical Examiners, Board of Nursing, and the Board of Pharmacy. However, appropriate prescribing of opioid analgesics should be encouraged by all of those involved in patient care. Both the physician or other healthcare provider and the pharmacist share responsibility for appropriate prescribing of opioid pain medication. The Board of Medical Examiners has established a policy for appropriate treatment of chronic pain, which is outlined below. With use of these guidelines and appropriate communication between practitioners and pharmacists, inappropriate use of opioid pain medications will be minimized. If a pharmacist has suspicion of the inappropriateness of a pain medication, he or she should contact the practitioner concerning this issue.

Treatment of chronic pain is multifactorial and treatment with modalities other than opioids should usually be utilized before opioids are prescribed. The use of alternative types of treatment should be considered periodically to reassess the necessity of continued opioid use. The following guidelines have been provided in the form of a policy letter from the Board of Medical Examiners to providers in the state:

Board of Medical Examiners recommendations:

• **Thorough history and physical examination**. Included in the history is assessment of the etiology of pain, physical and psychological function of the patient, substance abuse history, other treatments that have been attempted to control the patient's level of pain, identification of underlying or co-existing diseases or conditions and, as much as possible, statements by all treating physicians that the patient's pain is intractable and not controlled by other than the use of opioid analgesics.

• **Treatment plan**. A thoroughly documented, written treatment plan should be established and should include how treatment success will be evaluated, such as pain relief and improved physical or psychological functioning. Several treatment modalities should be utilized in most cases and should be done concurrently with the use of opiates. Periodic review by the physician should be accomplished to determine that there are no other appropriate treatment methods that would then be of additional benefit to the patient.

• **Informed consent**. The physician should discuss the risks and benefits of the use of controlled substances with the patient and/or guardian and this should be accomplished on an ongoing basis, not just at the initiation of treatment.

• **Appropriate referral**. If treatment objectives are not being realized or if patients appear to be at risk for misuse of medications, referral should be made to appropriate specialists including addiction medicine specialists and chronic pain specialists.

• **Documentation**. All the above recommendations and guidelines should be recorded accurately and completely in the patient's medical record.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

A pharmacist evaluating a controlled substance prescription should consider the following points:

- Are you able to verify the identity of the prescriber and the patient?
- What is the physical condition and demeanor of the patient with respect to the drug being prescribed? Is the prescribed drug therapeutically appropriate to the patient's diagnosis?
- Does the patient live within the general area of the pharmacy? If not, is the distance great enough to make it unlikely the patient would travel so far to fill a legitimate prescription?
- Does the drug prescribed have a pattern of abuse, and does the patient have any known history of drug abuse or misuse that might contraindicate the use of this drug?
- Is the prescription consistent with the prescribing patterns of the practitioner, including the type and amount of drug prescribed? Does the practitioner write for a greater than usual percentage of controlled substances? Are you aware of any prior disciplinary or criminal action involving the practitioner?
- Are the drugs prescribed consistent with the practitioner's specialty and scope of practice? Does the prescription contain an unusual combination of drugs, or drugs that antagonize one another?
- Does the quantity of drug prescribed and refills authorized differ appreciably from recognized and accepted prescribing practices?

Studies have shown that the abuse potential of opioids is generally low in healthy volunteers who do not abuse drugs. Practitioners are encouraged to reverse the trend of under treatment of pain, yet remain aware of the dangers of diversion and nonmedical use of controlled substances. It is imperative the pharmacists and prescribers continue to strive for open and clear lines of communication regarding their patient's use and possible misuse of medications. The Board of Medical Examiners, Nursing and Pharmacy seek to assure that no Montana resident will needlessly suffer due to under treated pain and encourage both prescribers and pharmacists to do their part by responsibly prescribing and dispensing opioids.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that efforts to reduce the abuse and diversion of controlled substances should not interfere with legitimate medical use.

(+) *CRITERION 4:*
Encourages pain management

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NE

NEBRASKA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Chapter 28. Crimes and Punishments; Article 4. Drugs and Narcotics

- MEDICAL PRACTICE ACT
  Chapter 71. Public Health and Welfare; Article 1. Licenses; Professional and Occupational; (o) Practice of Medicine and Surgery

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Chapter 71. Public Health and Welfare; Article 1. Licenses; Professional and Occupational; (r) Practice of Osteopathy

- PHARMACY PRACTICE ACT (*No provisions found*)
  Chapter 71. Public Health and Welfare; Article 1. Licenses; Professional and Occupational; (s) Practice of Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  No policy found

- MEDICAL BOARD REGULATIONS (*Governs Osteopathic Board*)
  Title 172. Professional and Occupational Licensure (Department of Health and Human Services); Chapter 88. Regulations Governing the Practice of Medicine and Surgery and Osteopathic Medicine and Surgery

- PHARMACY BOARD REGULATIONS
  Title 172. Professional and Occupational Licensure (Department of Health and Human Services); Chapter 128. Practice of Pharmacy

  Title 175. Health Care Facilities and Services Licensure (Department of Health and Human Services); Chapter 8. Pharmacies

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Nebraska Board of Medicine and Surgery. *Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted: June 3, 2005.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- PROFESSIONAL PRACTICE
  Chapter 71. Public Health and Welfare; Article 1. Licenses; Professional and Occupational; (a) Definitions – (j) Licensee Assistance Program

- PAIN MANAGEMENT ACT
  Chapter 71. Public Health and Welfare; Article 24. Drugs; (d) Pain Management

- HOSPICE SERVICES
  Title 175. Health Care Facilities and Services Licensure (Department of Health and Human Services); Chapter 16. Hospice Services

NE

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act		●						
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[2]								
Medical Board[1]								
Pharmacy Board		●						
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Professional Practice		●						
Pain Management Act	●	●	●	●	●	●		●
Hospice Services								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9 Opioids are a last resort	10 Implies opioids are not part of professional practice	11 Physical dependence or analgesic tolerance confused with "addiction"	12 Medical decisions are restricted	13 Length of prescription validity is restricted	14 Undue prescription requirements	15 Other provisions that may impede pain management	16 Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[2]								
Medical Board				●				
Pharmacy Board				●				
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Professional Practice[1]								
Pain Management Act[1]								
Hospice Services[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

NEBRASKA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

R.R.S. Neb. § 28-401

§ 28-401. Terms, defined

As used in the Uniform Controlled Substances Act, unless the context otherwise requires:

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(20) Practitioner shall mean a physician, a physician assistant, a dentist, a veterinarian, a pharmacist, a podiatrist, an optometrist, a certified nurse midwife, a certified registered nurse anesthetist, a nurse practitioner, a scientific investigator, a pharmacy, a hospital, or any other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe, conduct research with respect to, or administer a controlled substance in the course of practice or research in this state, including an emergency medical service as defined in section 71-5175;

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(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

R.R.S. Neb. § 71-1,102

§ 71-1,102. Practice of medicine and surgery, defined

For the purpose of the Uniform Licensing Law, and except as otherwise provided by law, the following classes of persons shall be deemed to be engaged in the practice of medicine and surgery: (1) Persons who publicly profess to be physicians, surgeons, or obstetricians, or publicly profess to assume the duties incident to the practice of medicine, surgery, or obstetrics, or any of their branches; (2) persons who prescribe and furnish medicine for some illness, disease, ailment, injury, pain, deformity, or any physical or mental condition, or treat the same by surgery; (3) persons holding themselves out to the public as being qualified in the diagnosis or treatment of diseases, ailments, pain, deformity, or any physical or mental condition, or injuries of human beings; (4) persons who suggest, recommend, or prescribe any form of treatment for the intended palliation, relief, or cure of any physical or mental ailment of any person; (5) persons who maintain an office for the examination or treatment of persons afflicted with ailments, diseases, injuries, pain, deformity, or any physical or mental condition of human beings; (6) persons who attach to their name the title of M.D., surgeon, physician, physician and surgeon, or any word or abbreviation indicating that they are engaged in the treatment or diagnosis of ailments, diseases, injuries, pain, deformity, infirmity, or any physical or mental condition of human beings; and (7) persons who are physically located in another state but who, through the use of any medium, including an electronic medium, perform for compensation any service which constitutes the healing arts that would affect the diagnosis or treatment of an individual located in this state, unless he or she is providing consultation services to a physician and surgeon who is duly licensed in this state and is a treating physician of the individual. For purposes of this subdivision, consultation means the evaluation of the medical data of the patient as provided by the treating physician and rendering a recommendation to such treating physician as to the method of treatment or analysis of the data.

(+) *CRITERION 2:*
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEBRASKA

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Nebraska Admin. Code Title 172, Ch. 88

CHAPTER 88. REGULATIONS GOVERNING THE PRACTICE OF MEDICINE AND SURGERY AND OSTEOPATHIC MEDICINE AND SURGERY

001 SCOPE OF REGULATIONS These regulations are intended to implement the laws governing the practice of Medicine and Surgery and Osteopathic Medicine and Surgery pursuant to Neb. Rev. Stat. '' 71-1,102 to 71-1,107.30, 71-1,137 to 71-1,141 and the Uniform Licensing Law.

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88-013 UNPROFESSIONAL CONDUCT: This section defines the following acts as unprofessional conduct, pursuant to Neb. Rev. Stat. '71-148(22), and where applicable, further construes the unlawful or unprofessional acts listed in Neb. Rev. Stat. '' 71-147 and 71-148.

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12. Except as otherwise permitted by law, prescribing, selling, administering, distributing, ordering, or giving to an addict or any person previously drug dependent, any drug legally classified as a controlled substance;

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(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

COMMENT: Nebraska law does not seem to create an exemption for patients with pain and a history of addiction.

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Nebraska Admin. Code Title 175, Ch. 8

CHAPTER 8. PHARMACIES

8-001 SCOPE AND AUTHORITY: These regulations govern licensure of Pharmacies. The regulations are authorized by and implement the Health Care Facility Licensure Act, *Neb. Rev. Stat. sections 71-401* to 71-462.

8-002 DEFINITIONS

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(+) *CRITERION 2:*
Pain management is part of medical practice

Healing arts means a health profession in which a licensed practitioner offers or undertakes to diagnose, treat, operate on, or prescribe for any human pain, injury, disease, deformity, or physical or mental condition.

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128-009 UNPROFESSIONAL CONDUCT: In addition to the unlawful or unprofessional acts listed in *Neb. Rev. Stat. §§ 71-147* through *71-148*, the following conduct will be considered unprofessional acts as defined by the Board per *Neb. Rev. Stat. § 71-147(10)*:

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7. Except as otherwise permitted by law, dispensing, selling, administering, distributing, ordering, or giving to a person, known by the pharmacist to be an addict or any person previously drug dependent, any drug legally classified as a controlled substance;

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(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

COMMENT: Nebraska law does not seem to create an exemption for patients with pain and a history of addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEBRASKA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 4:*
Encourages pain management

GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Section I: Preamble

The Nebraska Board of Medicine and Surgery recognizes that principles of quality medical practice dictate that the people of the State of Nebraska have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(+) *CRITERION 2:*
Pain management is part of medical practice

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

The Nebraska Board of Medicine and Surgery is obligated under the laws of the State of Nebraska to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEBRASKA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements and
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the *Physicians Manual of the U.S. Drug Enforcement Administration* and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEBRASKA

STATUTES

Professional Practice

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

R.R.S. Neb. § 71-101.01

§ 71-101.01. Healing art, defined

Whenever the term healing art or healing arts is used in any statute, unless such statute specifically designates otherwise, it shall be construed to refer exclusively to a health profession in which a licensed practitioner offers or undertakes to diagnose, treat, operate on, or prescribe for any human pain, injury, disease, deformity, or physical or mental condition. Nothing in this section shall be construed to enlarge the scope or definition for practice of any practitioner licensed in accordance with Chapter 71, article 1.

(+) CRITERION 2:
Pain management is part of medical practice

STATUTES

Pain Management Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

R.R.S. Neb. § 71-2418

§ 71-2418. Legislative findings

(1) The Legislature finds that many controlled substances have useful and legitimate medical and scientific purposes and are necessary to maintain the health and general welfare of the people of Nebraska. Principles of quality medical practice dictate that the people of Nebraska have access to appropriate and effective pain relief.

(2) The Legislature finds that the appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain. The Legislature therefore encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, including those patients who experience pain as a result of terminal illness.

(3) The Legislature finds that a physician should be able to prescribe, dispense, or administer a controlled substance in excess of the recommended dosage for the treatment of pain so long as such dosage is not administered for the purpose of causing, or the purpose of assisting in causing, death for any reason and so long as it conforms to policies and guidelines for the treatment of pain adopted by the Board of Examiners in Medicine and Surgery.

(4) The Legislature finds that a health care facility, hospice, or third-party payor should not forbid or restrict the use of controlled substances appropriately administered for the treatment of pain.

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R.R.S. Neb. § 71-2420

§ 71-2420. Board of Examiners in Medicine and Surgery; duties

The Board of Examiners in Medicine and Surgery shall adopt policies and guidelines for the treatment of pain to ensure that physicians who are engaged in the appropriate treatment of pain are not subject to disciplinary action, and the board shall consider policies and guidelines developed by national organizations with expertise in pain management for this purpose.

(+) CRITERION 1:
Controlled substances are necessary for public health

(+) CRITERION 4:
Encourages pain management

(+) CRITERION 6:
Prescription amount alone does not determine legitimacy

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Attempts to provide a secure environment for physicians prescribing in their healthcare facility.

(+) CRITERION 5:
Addresses fear of regulatory scrutiny

(+) CRITERION 3:
Opioids are part of professional practice

(+) CRITERION 2:
Pain management is part of medical practice

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEBRASKA

REGULATIONS

Hospice Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Nebraska Admin. Code Title 175, Ch. 16

CHAPTER 16. HOSPICE SERVICES

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16-006 STANDARDS OF OPERATION, CARE, AND TREATMENT: Each hospice must be organized to promote the attainment of its objectives and purposes. The major organizational divisions in each hospice must include a governing authority, administration, and a medical staff. In addition, the basic organization, responsibility, and operation of each licensed hospice must assure adequate protection to hospice patients and compliance with state statutes.

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16-006.06 Patient Rights: The governing authority must establish a bill of rights that will be equally applicable to all patients. The hospice must protect and promote the exercise of these rights. Patients must have the right to:

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15. Expect pain relief. Measures will be instituted to ensure comfort;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (patient bill of rights) for hospices to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NV

NEVADA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 40. Public Health and Safety; Chapter 453. Controlled Substances

- MEDICAL PRACTICE ACT
  Title 54. Professions, Occupations, and Businesses; Chapter 630. Physicians, Physician Assistants, and Practitioners of Respiratory Care

- OSTEOPATHIC PRACTICE ACT
  Title 54. Professions, Occupations, and Businesses; Chapter 633. Osteopathic Medicine

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 54. Professions, Occupations, and Businesses; Chapter 639. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Chapter 453. Controlled Substances
  Chapter 458. Abuse of Alcohol and Drugs

- MEDICAL BOARD REGULATIONS
  Chapter 630. Physicians, Physician Assistants, and Practitioners of Respiratory Care

- OSTEOPATHIC BOARD REGULATIONS
  Chapter 633. Osteopathic Medicine

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Chapter 639. Pharmacists and Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

No policies found

NV

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act		●	●					●
Medical Practice Act					●			
Osteopathic Practice Act					●			
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board		●	●	●	●	●	●	●
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES[2]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act			●			●		
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board		●		●				●
Osteopathic Board								●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES[2]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

NEVADA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Nev. Rev. Stat. Ann. § 453.098 - 453.099

§ 453.098. "Narcotic addict" defined

"Narcotic addict" means a person of any age who has developed a compulsion to continue taking or who has developed a psychic or physical dependence on the effects of a narcotic drug.

§ 453.099. "Narcotic addiction" defined

"Narcotic addiction" means compulsion to continue taking or psychic or physical dependence on the effects of a narcotic drug.

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

Nev. Rev. Stat. Ann. § 453.256

§ 453.256. Prescriptions; requirements for dispensing certain substances; penalty

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9. As used in this section:

(a) "Facsimile machine" means a device which sends or receives a reproduction or facsimile of a document or photograph which is transmitted electronically or telephonically by telecommunications lines.

(+) *CRITERION 2:*
Pain management is part of medical practice

(b) "Medical treatment" includes dispensing or administering a narcotic drug for pain, whether or not intractable.

(+) *CRITERION 3:*
Opioids are part of professional practice

(c) "Parenteral solution" has the meaning ascribed to it in NRS 639.0105

Nev. Rev. Stat. Ann. § 453.257

§ 453.257. Filling second or subsequent prescriptions

A pharmacist shall not fill a second or subsequent prescription for a controlled substance listed in Schedule II for the same patient unless the frequency of prescriptions is in conformity with the directions for use. The need for any increased amount shall be verified by the practitioner in writing or personally by telephone.

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(-) *CRITERION 14:*
Undue prescription requirements

COMMENT: Appears to require verification of any subsequent Schedule II prescription which includes any increased amount.

Nev. Rev. Stat. Ann. § 453.1545

453.1545. Board and division required to develop computerized program to track prescriptions for controlled substances; reporting of illegal activity; confidentiality of information obtained from program; gifts, grants and donations.

1. The Board and the Division shall cooperatively develop a computerized program to track each prescription for a controlled substance listed in schedule II, III or IV that is filled by a pharmacy that is registered with the Board or that is dispensed by a practitioner who is registered with the Board. The program must:

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that a prescription monitoring program should not interfere with legitimate medical use of controlled substances.

(c) Not infringe on the legal use of a controlled substance for the management of severe or intractable pain.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Nev. Rev. Stat. Ann. § 630.3066

630.3066. Prescribing or administering certain controlled substances for treatment of intractable pain not grounds for initiating disciplinary action.

A physician is not subject to disciplinary action solely for:

1. Prescribing or administering to a patient under his care a controlled substance which is listed in schedule II, III, IV or V by the state board of pharmacy pursuant to *NRS 453.146*, if the controlled substance is lawfully prescribed or administered for the treatment of intractable pain in accordance with regulations adopted by the board.

2. Engaging in any activity in accordance with the provisions of chapter 453A of NRS.

(+) *CRITERION 5: Addresses fear of regulatory scrutiny*

STATUTES

Osteopathic Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Nev. Rev. Stat. Ann. § 633.521

633.521. Prescribing or administering certain drugs or controlled substances or engaging in activity relating to medical use of marijuana not grounds for disciplinary action under certain circumstances.

An osteopathic physician is not subject to disciplinary action solely for:

1. Prescribing or administering to a patient under his care:

(a) Amygdalin (laetrile), if the patient has consented to the use of the substance.

(b) Procaine hydrochloride with preservatives and stabilizers (Gerovital H3).

(c) A controlled substance which is listed in schedule II, III, IV or V by the State Board of Pharmacy pursuant to *NRS 453.146*, if the controlled substance is lawfully prescribed or administered for the treatment of intractable pain in accordance with accepted standards for the practice of osteopathic medicine.

2. Engaging in any activity in accordance with the provisions of chapter 453A of NRS.

(+) *CRITERION 5: Addresses fear of regulatory scrutiny*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

NAC 630.187

630.187 Adoption by reference of Model Guidelines for the Use of Controlled Substances for the Treatment of Pain. (NRS 630.130)

1. The board hereby adopts by reference the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain, May 1998, published by the Federation of State Medical Boards of the United States, Inc., and any subsequent revision of the publication that has been approved by the board for use in this state. Each revision of the publication shall be deemed approved by the board unless it disapproves of the revision within 60 days after the date of publication of the revision.

2. The most recent publication of the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain that has been approved by the board will be available for inspection at the office of the Board of Medical Examiners, 1105 Terminal Way, Suite 301, Reno, Nevada or may be obtained, free of charge, from the Federation of State Medical Boards of the United States, Inc., Federation Place, 400 Fuller Wiser Road, Suite 300, Euless, Texas 76039-3855 or from the Federation of State Medical Boards of the United States, Inc., at the Internet address http://www.fsmb.org/pubform.htm. The board shall:

(a) Review each revision of the publication to ensure its suitability for this state; and

(b) File a copy of each revision of the publication it approves with the secretary of state and the state library and archives administrator.

MODEL GUIDELINES FOR THE USE OF
CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Section I: Preamble

The Nevada Board of Medical Examiners recognizes that principles of quality medical practice dictate that the people of the State of Nevada have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as to reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the *U.S. Agency for Health Care and Research Clinical Practice Guidelines* for a sound approach to the management of acute[1] pain and cancer-related[2] pain. The medical management of pain should be based upon current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

The Nevada Board of Medical Examiners is obligated under the laws of the State of Nevada to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

(+) *CRITERION 3:*
Opioids are part of professional practice

Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs - including any improvement in functioning - and recognizing that some types of pain cannot be completely relieved.

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for additional flexibility for physicians as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. *Evaluation of the Patient.*

A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance.

2. *Treatment Plan.*

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

3. *Informed Consent and Agreement for Treatment*.

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities including

1.urine/serum medication levels screening when requested

2.number and frequency of all prescription refills; and

3. reasons for which drug therapy may be discontinued (i.e. violation of agreement).

4. *Periodic Review*.

At reasonable intervals based upon the individual circumstance of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should re-evaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. *Consultation.*

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

6. *Medical Records*.

The physician should keep accurate and complete records to include (1) the medical history and physical examination; (2) diagnostic, therapeutic and laboratory results; (3) evaluations and consultations; (4) treatment objectives; (5) discussion of risks and benefits; (6) treatments; (7) medications (including date, type, dosage, and quantity prescribed); (8) instructions and agreements; and (9) periodic reviews. Records should remain current, and be maintained in an accessible manner, and readily available for review.

7. *Compliance with Controlled Substances Laws and Regulations*.

To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state, and comply with applicable federal and state regulations. Physicians are referred to *the Physicians Manual of the U.S. Drug Enforcement Administration* and applicable state regulations for rules governing controlled substances.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

***Acute pain*:** Acute pain is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

***Addiction*:** Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

***Analgesic Tolerance*:** Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain: A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain: An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence: Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction: Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse: Substance abuse is the use of any substance(s) for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.

Tolerance: Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose.

References:

1. Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.

2. Jacox A, Carr DB, Payne R. et al. Management of Cancer Pain. Clinical Practice Guideline No. 9. AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research, U.S. Department of Health and Human Resources, Public Health Service. March 1994.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEVADA

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

NAC 630.230

NAC 630.230 Prohibited professional conduct.

1. A person who is licensed as a physician or physician assistant shall not:

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(l) Engage in the practice of writing prescriptions for controlled substances to treat acute pain or chronic pain in a manner that deviates from the guidelines set forth in the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* adopted by reference in NAC 630.187.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY C:
Conflicting or inconsistent policies or provisions

COMMENT: Contradicts the flexibility standards inherent in the *Model Guidelines.*

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

NAC 630.255

NAC 630.255 Exemption from grounds: "Intractable pain" defined. (NRS 630.135)

For the purposes of NRS 630.3066, “intractable pain” means a condition of discomfort for which the cause cannot be removed or otherwise treated and for which a method of providing relief, or of which a cure for the cause, has not been found after reasonable efforts have been taken in accordance with accepted standards for the practice of medicine, including, but not limited to, evaluation by an attending physician and one or more physicians specializing in the treatment of the area, system, or organ of the body which is believed to be the source of the discomfort.

(-) *CRITERION 10:*
Implies opioids are not part of professional practice

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY B:
Mandated consultation

REGULATIONS

Osteopathic Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

NAC 633.350

633.350 Unethical conduct.

For the purposes of this chapter and chapter 633 of NRS, a licensee engages in unethical conduct if he:

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6. Prescribes a controlled substance in a manner or an amount that the board determines is excessive;

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: “Excessive” implies a limit, but the limit is not specified.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NH

NEW HAMPSHIRE

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title XXX. Occupations and Professions; Chapter 318-B. Controlled Drug Act

- MEDICAL PRACTICE ACT
  Title XXX. Occupations and Professions; Chapter 329. Physicians and Surgeons

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title XXX. Occupations and Professions; Chapter 318. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Department of Health and Human Services; Commissioner; Chapter He-C 500. Public Health and Safety;

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Board of Medicine

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Pharmacy Board

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  New Hampshire Board of Medicine. Guidelines for the Use of Controlled Substances in the Management of Chronic Pain. Adopted: May 11, 2000.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- REQUIRED SERVICES
  Department of Health and Human Services; Division of Public Health; Chapter He-P 800. Residential Care and Health Facility Rules; Part He-P 805. Assisted Living Residence-Supported Residential Health Care Licensing

NH

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					●
Medical Practice Act								●
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●		●	●	●		●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Required Services								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act				●				●
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Required Services[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

NEW HAMPSHIRE

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

RSA § 318-B:1

§ 318-B:1. Definitions

The following words and phrases, as used in this chapter, shall have the following meanings, unless the context otherwise requires:

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IX. "Drug dependence" means a state of physical addiction or psychic dependence, or both, upon a drug following use of that drug upon a repeated periodic or continuous basis except:

(a) Upon a morphine-type drug as an incident to current medical treatment of a demonstrable physical disorder, other than produced by the use of the drug itself, or

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X. "Drug-dependent person" means any person who has developed a state of psychic or physical dependence, or both, upon a controlled drug following administration of that drug upon a repeated periodic or continuous basis. No person shall be classified as drug dependent who is dependent:

(a) Upon a morphine-type drug as an incident to current medical treatment of a demonstrable physical disorder other than drug dependence, or

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RSA § 318-B:9

§ 318-B:9. Sale by Pharmacists

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IV. No prescription shall be filled for more than a 34-day supply or 100 dosage units, whichever is less, upon any single filling for controlled drugs of schedules II or III;

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RSA § 318-B:10

§ 318-B:10 Professional Use of Narcotic Drugs.

I. A practitioner other than a veterinarian, in good faith, in the course of his professional practice, and for a legitimate medical purpose, may administer and prescribe controlled drugs, or the practitioner may cause the same to be administered by a nurse or intern under his direction and supervision. In a bona fide emergency situation, the practitioner may dispense a controlled drug to a patient under his care but only in a quantity not to exceed a 48-hour supply for all schedule II substances or a 7-day supply of schedule III, IV, or V substances.

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IX. If, in the judgment of a physician licensed under RSA 329, appropriate pain management warrants a high dosage of controlled drugs and the benefit of the relief expected outweighs the risk of the high dosage, the licensed physician may administer or cause to be administered such a dosage, even if its use may increase the risk of death, so long as it is not furnished for the purpose of causing, or the purpose of assisting in causing, death for any reason and so long as it falls within rules of the board of medicine.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Would a "demonsratable physical disorder" include a chronic condition with an undiagnosable etiology?

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY C:
Restrictions regarding quantity prescribed or dispensed

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exemption of certain patients from being labeled either "drug dependent" or a "drug dependent person" nevertheless continues to allow other patients to be labeled as such.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEW HAMPSHIRE

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

RSA 329:9

329:9 Rulemaking Authority.

The board shall adopt rules, pursuant to *RSA 541-A*, relative to:

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XV. Procedural and substantive requirements for assessing, compromising and collecting administrative fines against licensees as authorized under *RSA 329:17*, VII(g) and against licensees and nonlicensees as authorized by *RSA 329:2*, II(d).

XV-a. Procedures for appropriate pain management pursuant to *RSA 318-B:10*, IX.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (adopt rules) for the Board to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

New Hampshire Board of Medicine

May 11, 2000

Dear Physician:

The New Hampshire Board of Medicine has adopted guidelines for pain management in hopes of fostering the best pain treatment for the citizens of this State. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, be it acute or chronic, due to either malignant or benign disease, and particularly when associated with terminal illness. For many physicians, fear of investigation or sanction for dispensing large or prolonged narcotic prescriptions has impeded effective and appropriate treatment. Accordingly, these guidelines have been developed to clarify the Board's position of pain control specifically as related to the use of controlled substances, to alleviate physician uncertainty, and to encourage better pain management. This format was derived from many sources including N.H. Physicians specializing in pain management, the N.H. State Medical Society, and the Federation of State Medical Boards.

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing or administering controlled substances for a legitimate medical purpose and in the usual course of professional practice. The Board has concern in those cases where inadequate pain control results from either lack of current knowledge of pain management or inappropriate fear of investigation for providing narcotics where indicated.

The N.H. Board remains obligated under the laws of the State of New Hampshire to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Improper prescribing or documentation will continue to be investigated.

The guidelines are not rigid rules. They serve as a model for physician practice, and to communicate what the Board considers to be within the boundaries of professional practice. While the Board will likely not take disciplinary action against a physician for failing to adhere strictly to the provisions of this protocol, "significant deviation" from the guidelines will likely result in investigation and/or sanction of a physician practice. Key features of the guidelines include accurate documentation, some form of a treatment plan, acceptance of the plan by the patient, and appropriate evaluations and/or consultations. Compliance with all controlled substances laws and regulations is mandatory.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work related factors. This Board hopes to encourage superior pain management by physicians, and clarify appropriate pain relieving practice with the institution of these guidelines.

Sincerely,

The New Hampshire Board of Medicine

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to patients

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 4:*
Pain management is encouraged

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES IN THE MANAGEMENT OF CHRONIC PAIN

1. Evaluation of the Patient

An accurate and complete medical history and physical examination must be documented in the medical record. The medical record should document the nature and intensity of the pain and relevant coexisting condition (including current or past substance abuse.) The results of relevant diagnostic studies, other evaluations and consults should be part of the record.

Treatment Plan

A treatment plan should state objectives that will be used to determine treatment success, such as pain relief, and/or improved physical or psycho social function. The record should indicate if any further diagnostic evaluations or treatments are planned. Other treatment modalities might include a rehabilitation program, physical therapy or the like, or other treatment plan deemed appropriate for the patient's treatment objectives. After treatment begins, the physician should adjust drug therapy to the individual needs of each patient.

Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, appropriate significant other, and/or guardian. The patient should receive prescriptions from one physician and one pharmacy when chronic narcotic use is adopted, and should authorize communication between both parties. Frequently, the physician may elect to use a written agreement with the patient, especially where rick of medication abuse is a concern. A written agreement may; (1) indicate a specific pharmacy and prescribing physician; (2) give permission for communication between care providers; (3) detail amount and frequency of medication and prescription refills; (4) define expected follow-up and participation in any other pain treatment activities; (5) provide reasons for which opioid therapy may be discontinued; (6) include an agreement to have urine/serum medication or drug levels/screens when requested; and (7) document other inclusions appropriate for management of the individual patient.

Periodic Review

At reasonable intervals, the physician should review the course of opioid treatment and any new information about the etiology and the impact of the pain. Continuation or modification of opioid therapy should depend on the physician's evaluation of progress toward stated treatment objectives. If reasonable treatment goals are not being achieved, despite medication adjustments, the physician should monitor patient compliance in medication usage and related treatment plans.

Consultation

The physician should refer the patient for additional evaluation and treatment as necessary and reasonable in order to achieve adequate control of the pain and any other treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse, or with comorbid psychiatric disorder, requires extra care in structuring, monitoring, and documentation. When indicated and available, consultation with, or referral to, an expert in the management of chronic pain is advised.

Medical Records

The physician should keep accurate and complete records to include documentation of; (1) medical history and physical examination; (2) relevant diagnostic, therapeutic and laboratory results; (3) results of evaluation and consultation; (4) treatment objectives; (5) discussion of risks and benefits; (6) treatments and treatment responses; (7) medications (including date, type, dosage, refills, and quantity prescribed); (8) instructions and agreements; and (9) periodic reviews. Records should remain current, be maintained in an accessible manner an be readily available for review.

Compliance with Controlled Substances Law and Regulations

To prescribe controlled substances the physician must be licensed in the State of New Hampshire, have valid controlled substances registration and comply with federal and state regulation for issuing controlled substances prescriptions. Physicians should refer to the federal, state and local regulatory agencies for guidance, by writing the Board of Medicine, 2 Industrial Park Drive, Concord, New Hampshire 03301.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEW HAMPSHIRE

REGULATIONS

Required Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.H. Admin. Rules, He-P 805.16

He-P 805.16 Required Services.

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(h) The nursing assessment, completed in accordance with (g) above, shall include:

(1) A medication review;

(2) A review of the resident's clinical record; and

(3) Assessment for pain, vital signs, physical, cognitive, mental and behavioral status, as well as an assessment as to how the resident is psychologically adapting to his or her social environment.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (assessment) for residential healthcare facilities to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NJ

NEW JERSEY

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 24. Food and Drugs; Subtitle 3. Dangerous Substances and narcotic Drugs; Chapter 21. Dangerous Substances Control

- MEDICAL PRACTICE ACT
  Title 45. Professions and Occupations; Subtitle 1. Professions and Occupations Subject to State Boards of Registration and Examination; Chapter 9. Physicians and Surgeons

- PHARMACY PRACTICE ACT
  Title 45. Professions and Occupations; Subtitle 1. Professions and Occupations Subject to State Boards of Registration and Examination; Chapter 14. Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 8. Department of Health and Senior Services; Chapter 65. Controlled Dangerous Substances

- MEDICAL BOARD REGULATIONS
  Title13. Law and Public Safety. Chapter 35. Board of Medical Examiners

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title13. Law and Public Safety. Chapter 39. State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policy found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- CODE OF CRIMINAL JUSTICE
  Title 2C. The New Jersey Code of Criminal Justice; Subtitle 2. Specific Offenses; Part 5. Offenses Against the Public, Public Order, Health and Decency; Chapter 5. Controlled Substances

- HEALTH CARE FACILITIES
  Title 26. Health and Vital Statistics; Chapter 2H. Health Care Facilities

- NURSING HOMES
  Title 30. Institutions and Agencies; Subtitle 8. Nursing Homes in General

- LICENSING STANDARDS FOR ASSISTED LIVING FACILITIES
  Title 8. Department of Health and Senior Services; Chapter 36. Standards for Licensure of Assisted Living Residences, Comprehensive Personal Care Homes, and Assisted Living Programs

- LICENSING STANDARDS FOR LONG-TERM CARE FACILITIES
  Title 8. Department of Health and Senior Services; Chapter 39. Standards for Licensure of Long-Term Care Facilities

- LICENSING STANDARDS FOR AMBULATORY CARE FACILITIES
  Title 8. Department of Health and Senior Services; Chapter 43A. Manual of Standards for Licensing of Ambulatory Care Facilities

- PAIN MANAGEMENT PROCEDURES
  Title 8. Department of Health and Senior Services; Chapter 43E. General Licensure Procedures and Enforcement of Licensure Regulations

- LICENSING STANDARDS FOR HOSPITALS
  Title 8. Department of Health and Senior Services; Chapter 43G. Hospital Licensing Standards

- AIDS COMMUNITY CARE ALTERNATIVE PROGRAM SERVICES
  Title 10. Department of Human Services; Chapter 60. Home Care Services; Subchapter 7. AIDS Community Care Alternative Program

- LAW AND PUBLIC SAFETY
  Title 13. Law and Public Safety. Chapter 34C. Alcohol & Drug Counselor Committee

NJ

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act		●						
Pharmacy Practice Act			●					
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					
Medical Board		●						●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Code of Criminal Justice			●					
Health Care Facilities								●
Nursing Homes								●
Licensing Standards/ Assisted Living Facilities								●
Licensing Standards/Long-Term Care Facilities								●
Licensing Standards/ Ambulatory Care Facilities								●
Pain Management Procedures								●
Licensing Standards/Hospitals								●
AIDS Community Care Alternative Program Services								●
Law and Public Safety								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9 Opioids are a last resort	10 Implies opioids are not part of professional practice	11 Physical dependence or analgesic tolerance confused with "addiction"	12 Medical decisions are restricted	13 Length of prescription validity is restricted	14 Undue prescription requirements	15 Other provisions that may impede pain management	16 Provisions that are ambiguous
STATUTES								
Controlled Substances Act			●					
Medical Practice Act				●				
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances								●
Medical Board		●		●				●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Code of Criminal Justice[1]								
Health Care Facilities[1]								
Nursing Homes[1]								
Licensing Standards/Assisted Living Facilities[1]								
Licensing Standards/Long-Term Care Facilities[1]								
Licensing Standards/Ambulatory Care Facilities[1]								
Pain Management Procedures[1]								
Licensing Standards/Hospitals[1]								
AIDS Community Care Alternative Program Services[1]								
Law and Public Safety[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.J. Stat. § 24:21-2

§ 24:21-2. Definitions

Definitions. As used in this act:

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"Drug dependent person" means a person who is using a controlled dangerous substance and who is in a state of psychic or physical dependence, or both, arising from the use of that controlled dangerous substance on a continuous basis. Drug dependence is characterized by behavioral and other responses, including but not limited to a strong compulsion to take the substance on a recurring basis in order to experience its psychic effects, or to avoid the discomfort of its absence.

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"Practitioner" means a physician, dentist, veterinarian, scientific investigator, laboratory, pharmacy, hospital or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled dangerous substance in the course of professional practice or research in this State.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

N.J. Stat. § 45:9-5.1

§ 45:9-5.1. Definitions

Within the meaning of this chapter (45:9-1 et seq.), except as herein otherwise provided, and except for the purposes of the exemptions hereinafter contained in sections 45:9-14.1 to 45:9-14.10, inclusive, the phrase "the practice of medicine or surgery" and the phrase "the practice of medicine and surgery" shall include the practice of any branch of medicine and/or surgery, and any method of treatment of human ailment, disease, pain, injury, deformity, mental or physical condition, and the term "physician and surgeon" or "physician or surgeon" shall be deemed to include practitioners in any branch of medicine and/or surgery or method of treatment of human ailment, disease, pain, injury, deformity, mental or physical condition.

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N.J. Stat. § 45:9-14.3

§ 45:9-14.3. "Practice of osteopathy" defined; osteopathy license does not permit what

Within the meaning of the provisions of section *45:9-14.4*, the practice of osteopathy shall include the diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity, mental or physical condition; provided, however, that a license to practice osteopathy shall not permit the holder thereof to prescribe, administer or dispense drugs for internal use in the treatment of any human ailment, disease, pain, injury, deformity, mental or physical condition or to perform such surgical operations as require cutting.

(+) *CRITERION 2:*
Pain management is part of medical practice

N.J. Stat. § 45:9-22.19

§ 45:9-22.19. Schedule II controlled dangerous substance, prescription quantities.

(-) *CRITERION 12:*
Medical decisions are restricted

***CATEGORY C*:**
Restrictions regarding quantity prescribed or dispensed

A physician licensed pursuant to chapter 9 of Title 45 of the Revised Statutes may prescribe a Schedule II controlled dangerous substance for the use of a patient in any quantity which does not exceed a 30-day supply, as defined by regulations adopted by the State Board of Medical Examiners in consultation with the Department of Health and Senior Services. The physician shall document the diagnosis and the medical need for the prescription in the patient's medical record, in accordance with guidelines established by the State Board of Medical Examiners.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

N.J. Stat. § 45:14-41

§ 45:14-41. Definitions relative to pharmacists

As used in this act:

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"Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which the individual practices to administer or prescribe drugs in the course of professional practice.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.J.A.C. 8:65-7.2

§ 8:65-7.2 Definitions

The following words and terms when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

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"Individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States, the jurisdiction in which he practices, or in New Jersey, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

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(+) *CRITERION 3:*
Opioids are part of professional practice

N.J.A.C. 8:65-7.7

§ 8:65-7.7 Administering or dispensing of narcotic drugs

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(c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Does this imply that opioids are a treatment of last resort?

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.J.A.C. 13:35-6.19

§ 13:35-6.19 Duty to report changes in status

(a) The following words and terms, when used in this section, shall have the following meanings unless the context clearly indicates otherwise.

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"Health care facility" means a facility or institution, whether public or private, engaged in providing medical services, including diagnosis or treatment of human disease, pain, injury, deformity or physical condition, including, but not limited to, a general hospital, special hospital, mental hospital, health maintenance organizations, public health center, diagnostic center, treatment center, rehabilitation center, extended care facility, skilled nursing home, nursing home, intermediate care facility, tuberculosis hospital, chronic disease hospital, maternity hospital, outpatient clinic, dispensary, home health care agency, boarding home for the sheltered care of adult persons, and bio-analytical laboratory or central services facilities serving one or more such institutions but excluding institutions that provide healing solely by prayer.

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N.J.A.C. § 13:35-7.1

§ 13:35-7.1 Definitions

The following words and terms, when used in this subchapter shall have the following meanings unless the context clearly indicates otherwise.

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"Intractable pain" means pain which has been shown to be refractory or resistant to management with standard methods of treatment or for which insufficient relief has been found after reasonable efforts.

N.J.A.C. § 13:35-7.6

§ 13:35-7.6 Limitations on prescribing, administering or dispensing of controlled substances; special exceptions for management of pain

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(b) With respect to Schedule II controlled substances, unless the requirements of (c) below are met, a practitioner shall not authorize a quantity calculated to exceed 120 dosage units or a 30-day supply, whichever is less.

(c) A practitioner may exceed the 120 dosage unit or 30-day supply limitations for Schedule II controlled substances in (b) above in the following circumstances:

1. For the 120 dosage unit limitation, the practitioner follows a treatment plan designed to achieve effective pain management which has been tailored to the needs of a patient who is suffering pain from cancer, intractable pain or terminal illness. The treatment plan shall state objectives by which treatment success is to be evaluated, such as pain relief and improved physical and psychological function, and shall indicate if any further diagnostic evaluations or other treatments are planned. The practitioner shall discuss the risks and benefits of the use of controlled substances with the patient, guardian or authorized representative; and

2. With regards to the 30-day supply limitation, a practitioner may prescribe the use of an implantable infusion pump which is utilized to achieve pain management for patients suffering from cancer, intractable pain or terminal illness. A prescription for such an implantable infusion pump may provide up to a 90-day supply as long as the physician evaluates and documents the patient's continued need at least every 30 days.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of medical practice

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Does this imply that opioids are a treatment of last resort?

(-) *CRITERION 10:*
Implies opioids are not part of professional practice

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY C:
Restrictions regarding quantity prescribed or dispensed

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exemption of these patients from special prescription requirements nevertheless continues those requirements for all other patients.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 12:*
Medical decisions are restricted

***CATEGORY D*:**
Undue prescription limitations

COMMENT: "Drug holidays" are no longer recognized as appropriate medical practice.

[CONTINUED]

(d) When controlled substances are continuously prescribed for management of pain for three months or more, the practitioner:

1. Shall review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain and the patient's progress toward treatment objectives;

2. Shall remain alert to problems associated with physical and psychological dependence; and

3. Shall periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs such as nonsteroidal anti-inflammatories, or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.

(e) If treatment objectives are not being met, the practitioner:

1. Shall assess the appropriateness of continued treatment with controlled substances or undertake a trial of other drugs or treatment modalities; and

2. Shall consider referring the patient for independent evaluation or treatment in order to achieve treatment objectives.

(f) A practitioner shall remain alert to the possibility that controlled substances may be misused or diverted. A practitioner managing pain in a patient with a history of substance abuse shall exercise extra care by way of monitoring, documentation and possible consultation with addiction medicine specialists, and should consider the use of an agreement between the practitioner and the patient concerning controlled substance use and consequences for misuse.

(g) The practitioner shall keep accurate and complete records including that information required by (a) above as well as:

1. The medical history and physical examination of the patient;

2. Other evaluations and consultations;

3. Treatment plan objectives;

4. Evidence of informed consent;

5. Treatments and drugs prescribed or provided, as in (a) above;

6. Any agreements with the patient; and

7. Periodic reviews conducted.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Code of Criminal Justice

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

N.J. Stat. § 2C:35-2

§ 2C:35-2. Definitions

As used in this chapter:

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"Practitioner" means a physician, dentist, veterinarian, scientific investigator, laboratory, pharmacy, hospital or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled dangerous substance or controlled substance analog in the course of professional practice or research in this State.

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STATUTES

Health Care Facilities

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.J. Stat. § 26:2H-5b

§ 26:2H-5b. Routine monitoring of pain as fifth vital sign required

a. The Commissioner of Health and Senior Services shall prescribe, by regulation, requirements to be adopted by health care facilities licensed pursuant to P.L. 1971, c. 136 (*C. 26:2H-1* et seq.) for the routine monitoring of pain as a fifth vital sign in patients, in addition to blood pressure, pulse, respiration and temperature.

For the purpose of this subsection, the commissioner shall require health care facilities to:

(1) routinely inquire whether a patient is in pain;

(2) maintain policies and procedures as prescribed by the commissioner for asking patients to rate their degree of pain for a specified period of time and to record their responses; and

(3) routinely record levels of pain intensity on patient charts.

b. The requirements to be adopted pursuant to subsection a. of this section shall take effect no later than the 180th day after the effective date of this act.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (law regarding pain as fifth vital sign) for health care facilities to ensure that pain management is an essential part of patient care.

N.J. Stat. § 26:2H-12.8

§ 26:2H-12.8. Rights of persons admitted to a general hospital

Every person admitted to a general hospital as licensed by the State Department of Health and Senior Services pursuant to P.L. 1971, c. 136 (*C. 26:2H-1* et al.) shall have the right:

a. To considerate and respectful care consistent with sound nursing and medical practices, which shall include being informed of the name and licensure status of a student nurse or facility staff member who examines, observes or treats the patient and the right to expect and receive appropriate assessment, management and treatment of pain as an integral component of that person's care;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospitals to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Nursing Homes

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for nursing homes to ensure that pain management is an essential part of patient care.

N.J. Stat. § 30:13-5

§ 30:13-5. Rights of nursing home residents

Every resident of a nursing home shall:

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j. Have the right to a safe and decent living environment and considerate and respectful care that recognizes the dignity and individuality of the resident, including the right to expect and receive appropriate assessment, management and treatment of pain as an integral component of that person's care consistent with sound nursing and medical practices.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Licensing Standards for Assisted Living Facilities

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (staff orientation and education) for assisted living facilities to ensure that pain management is an essential part of patient care.

N.J.A.C. 8:36-5.6

§ 8:36-5.6 Staffing requirements

(a) The facility or program shall maintain and implement written staffing schedules. Actual hours worked by each employee shall be documented.
(b) The facility or program shall develop and implement a staff orientation and a staff education plan, including plans for each service and designation of person(s) responsible for training. All personnel shall receive orientation at the time of employment and at least annual in-service education regarding, at a minimum, the following:
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6. Pain management; and
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N.J.A.C. 8:36-4.1

§ 8:36-4.1 Posting and distribution of statement of resident rights

(a) Each assisted living provider will post and distribute a statement of resident rights for all residents of assisted living residences, comprehensive personal care homes, and assisted living programs. Each resident is entitled to the following rights:
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8. The right to receive pain management as needed, in accordance with N.J.A.C. 8:43E-6;
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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (statement of resident rights) for assisted living facilities to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Licensing Standards for Long-Term Care Facilities

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for long-term care facilities to ensure that pain management is an essential part of patient care.

N.J.A.C. 8:39-27.1

§ 8:39-27.1 Mandatory policies, procedures and practices for quality of care

(a) The facility shall provide and ensure that each resident receives all care and services needed to enable the resident to attain and maintain the highest practicable level of physical (including pain management), emotional and social well-being, in accordance with individual assessments and care plans.

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REGULATIONS

Licensing Standards for Ambulatory Care Facilities

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.J.A.C. 8:43A-16.2

§ 8:43A-16.2. Rights of each patient

(a) Each patient receiving services in an ambulatory care facility shall have the following rights:

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14. To expect and receive appropriate assessment, management and treatment of pain as an integral component of that person's care in accordance with N.J.A.C. 8:43E-6.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for ambulatory care facilities to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Pain Management Procedures

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (pain management standards) for healthcare facilities to ensure that pain management is an essential part of patient care.

N.J.A.C. 8:43E-6.1

§ 8:43E-6.1 Pain management standards; scope

The standards set forth in this subchapter apply to all health care facilities licensed in accordance with *N.J.S.A. 26:2H-1* et seq.

§ 8:43E-6.2 Purpose

The rules in this subchapter are intended to promote the health, safety, and welfare of patients or residents of health care facilities by establishing requirements for the assessment, monitoring and management of pain.

§ 8:43E-6.3 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

"Pain management" means the assessment of pain and, if appropriate, treatment in order to assure the needs of patients or residents of health care facilities who experience problems with pain are met. Treatment of pain may include the use of medications or application of other modalities and medical devices such as, but not limited to, heat or cold, massage, transcutaneous electrical nerve stimulation (TENS), acupuncture, and neurolytic techniques such as radiofrequency coagulation and cryotherapy.

"Pain rating scale" means a tool that is age cognitive and culturally specific to the patient or resident population to which it is applied and which results in an assessment and measurement of the intensity of pain.

"Pain treatment plan" means a plan, based on information gathered during a patient/resident pain assessment, that identifies the patient's/resident's needs and specifies appropriate interventions to alleviate pain, to the extent feasible and medically appropriate.

§ 8:43E-6.4 Pain assessment procedures

(a) A facility shall formulate a system for assessing and monitoring patients'/residents' pain using a pain rating scale.

1. A facility serving different patient/resident populations shall utilize more than one pain scale, as appropriate.

(b) Assessment of a patient's/resident's pain shall occur, at a minimum, upon admission, on the day of a planned discharge, and when warranted by changes in a patient's/resident's condition, self-reporting of pain and/or evidence of behavioral cues indicative of the presence of pain. In the case of individuals receiving home health care services, assessment shall coincide with a visit by staff of the home health service agency and assessment on the day of discharge is not required if the individual has been admitted to an inpatient or residential health care facility and discharge from the home health service agency takes place after the admission.

(c) If pain is identified, a pain treatment plan shall be developed and implemented within the health care facility or the patient/resident shall be referred for treatment or consultation.

(d) If the patient/resident is cognitively impaired or non-verbal, the facility shall utilize pain rating scales for the cognitively impaired and non-verbal patient/resident. Additionally, the facility shall seek information from the patient's/resident's family, caregiver or other representative, if available and known to the facility. The results of the pain rating scales and the response to the additional inquiry shall be documented in the patient's/resident's medical record.

(CONTINUED ON NEXT PAGE)

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Pain Management Procedures

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) ***CRITERION 8:***
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written policies and procedures) to provide patients information/education about pain management.

(CONTINUED)

(e) Pain assessment findings shall be documented in the patient's/resident's medical record. This shall include, but not be limited to, the date, pain rating, treatment plan and patient/resident response.

(f) The facility shall establish written policies and procedures governing the management of pain that are reviewed at least every three years and revised more frequently as needed. They shall include at least the following:

1. A written procedure for systematically conducting periodic assessment of a patient's/resident's pain, as specified in (b) above. At a minimum, the procedure must specify pain assessment upon admission, upon discharge, and when warranted by changes in a patient's/resident's condition and self-reporting of pain;

2. Criteria for the assessment of pain, including, but not limited to: pain intensity or severity, pain character, pain frequency or pattern, or both; pain location, pain duration, precipitating factors, responses to treatment and the personal, cultural, spiritual, and/or ethnic beliefs that may impact an individual's perception of pain;

3. A written procedure for the monitoring of a patient's/resident's pain;

4. A written procedure to insure the consistency of pain rating scales across departments within the health care facility;

5. Requirements for documentation of a patient's/resident's pain status on the medical record;

6. A procedure for educating patients/residents and, if applicable, their families about pain management when identified as part of their treatment; and

7. A written procedure for systematically coordinating and updating the pain treatment plan of a patient/resident in response to documented pain status.

§ 8:43E-6.5 Staff education and training programs

(a) Each facility shall develop, revise as necessary and implement a written plan for the purpose of training and educating staff on pain management. The plan shall include mandatory educational programs that address at least the following:

1. Orientation of new staff to the facility's policies and procedures on pain assessment and management;

2. Training of staff in pain assessment tools; behaviors potentially indicating pain; personal, cultural, spiritual and/or ethnic beliefs that may impact a patient's/resident's perception of pain; new equipment and new technologies to assess and monitor a patient's/resident's pain status;

3. Incorporation of pain assessment, monitoring and management into the initial orientation and ongoing education of all appropriate staff; and

4. Patient/resident rights.

(b) Implementation of the plan shall include records of attendance for each program.

§ 8:43E-6.6 Pain management continuous quality improvement

The facility's continuous quality improvement program shall include a systematic review and evaluation of pain assessment, management and documentation practices. The facility shall develop a plan by which to collect and analyze data in order to evaluate outcomes or performance. Data analysis shall focus on recommendations for implementing corrective actions and improving performance.

(+) ***CRITERION 8:***
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (training programs) to provide practitioners information/education about pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Licensing Standards for Hospitals

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written policies) for hospitals to ensure that pain management is an essential part of patient care

N.J.A.C. 8:43G-4.1

§ 8:43G-4.1. Patient rights

(a) Every New Jersey hospital patient shall have the following rights, none of which shall be abridged by the hospital or any of its staff. The hospital administrator shall be responsible for developing and implementing policies to protect patient rights and to respond to questions and grievances pertaining to patient rights. These rights shall include at least the following:

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31 To expect and receive appropriate assessment, management and treatment of pain as an integral component of that person's care, in accordance with N.J.A.C. 8:43E-6.

N.J.A.C. 8:43G-22.2

§ 8:43G-22.2 Pediatrics and pediatric intensive care policies and procedures

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(d) The pediatric services shall participate in developing anesthesia and pain management policies for infants and children.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

AIDS Community Care Alternative Program Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.J.A.C. 10:60-7.4

§ 10:60-7.4 ACCAP services

(a) All Medicaid or NJ KidCare-Plan A services, except for nursing facility services, are available under ACCAP in accord with an individualized plan of care. Additionally, the following services are available to the eligible beneficiary:

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7. Hospice care: This provides optimum comfort measures (including pain control), support and dignity to beneficiaries certified by an attending physician as terminally ill, with a life expectancy of up to six months. Family and/or other caregivers are also given support and direction while caring for the dying beneficiary. Services shall be provided by a Medicaid/NJ KidCare approved, Medicare certified hospice agency and available to a beneficiary on a daily, 24-hour basis. Hospice care shall be approved by the attending physician. Hospice services include: skilled nursing visits; hospice agency medical director services; medical social service visits; occupational therapy, physical therapy and speech-language pathology services; intravenous therapy; durable medical equipment; medication related to symptom control of terminal illness and case management. Reimbursement shall be at an established fee paid on a per diem basis.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that pain management is an essential part of hospice care.

REGULATIONS

Law and Public Safety

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.J.A.C. 13:34C-2.2

§ 13:34C-2.2 Application procedure: licensed clinical alcohol and drug counselor

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(b) An applicant shall furnish evidence that the applicant has:

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x. Pharmacology and physiology, which includes topics related to physiology of alcohol/drug use, abuse, dependency and addiction; neurophysiology of chemical use; psychopharmacology; therapeutic and appropriate use of pharmaceutical drugs; physical health and the use/abuse of drugs; psychiatric medications in the treatment of mental illness and dual diagnoses; appropriate use of prescribed medications for recovering chemically dependent clients/patients; treatment of chronic pain and clinical testing of body fluids and hair;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Requires AODA practitioners to receive information/education about pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NM

NEW MEXICO

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT (*No provisions found*)
  Chapter 30. Criminal Offenses; Article 31. Controlled Substances

- MEDICAL PRACTICE ACT
  Chapter 61. Professional and Occupational Licenses; Article 6. Medicine and Surgery

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Chapter 61. Professional and Occupational Licenses; Article 10. Osteopathic Medicine and Surgery

- PHARMACY PRACTICE ACT (*No provisions found*)
  Chapter 61. Professional and Occupational Licenses; Article11. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*)
  Title 16. Occupational and Professional Licensing; Chapter19. Pharmacists; Part 20. Controlled Substances

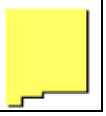
- MEDICAL BOARD REGULATIONS
  Title 16. Occupational and Professional Licensing; Chapter10. Medicine and Surgery Practitioners

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Title 16. Occupational and Professional Licensing; Chapter17. Osteopathic Medicine and Surgery Practitioners

- PHARMACY BOARD REGULATIONS (*No provisions found)*
  Title 16. Occupational and Professional Licensing; Chapter19. Pharmacists

OTHER GOVERNMENTAL POLICIES

- JOINT BOARD POLICY STATEMENT
  New Mexico Boards of Medical Practice, Nursing, and Pharmacy. Joint Statement on Management of Chronic Pain. Adopted: June 5, 2005.



RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- PAIN RELIEF ACT
  Chapter 24. Health and Safety; Article 2D. Pain Relief

- OPIOID TREATMENT PROGRAMS
  Title 7. Health; Chapter 32. Alcohol and Drug Abuse; Part 8. Opioid Treatment Programs

NM

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act		●						●
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					●
Medical Board		●	●	●	●	●	●	●
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Joint Board Policy Statement		●		●				●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Pain Relief Act					●	●		●
Opioid Treatment Programs								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board								●
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Joint Board Policy Statement[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Pain Relief Act[1]								
Opioid Treatment Programs[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

NEW MEXICO

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (guidelines) for the board to ensure that pain management is an essential part of patient care.

N.M. Stat. Ann. § 61-6-5

§ 61-6-5. Duties and powers. (Repealed effective July 1, 2010.)

The board shall:

. . .

O. establish and maintain rules related to the management of pain based on review of national standards for pain management.

. . .

N.M. Stat. Ann. § 61-6-6

§ 61-6-6. Definitions.

As used in Chapter 61, Article 6 NMSA 1978:

. . .

J. "the practice of medicine" consists of:

. . .

(5) offering or undertaking to diagnose, correct or treat in any manner or by any means, methods, devices or instrumentalities any disease, illness, pain, wound, fracture, infirmity, deformity, defect or abnormal physical or mental condition of any person;

. . .

(+) *CRITERION 2:*
Pain management is part of medical practice

N.M. Stat. Ann. § 61-6-15

§ 61-6-15. License may be refused, revoked or suspended; licensee may be fined, censured or reprimanded; procedure; practice after suspension or revocation; penalty; unprofessional and dishonorable conduct defined; fees and expenses. (Repealed effective July 1, 2010.)

. . .

D. "Unprofessional or dishonorable conduct", as used in this section, means, but is not limited to because of enumeration, conduct of a licensee that includes the following:

. . .

(35) undertreatment of pain as provided by board rule;

. . .

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes inadequate treatment of pain as subject to disciplinary action just as other substandard practices might be.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEW MEXICO

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

16.19.20.41 NMAC

§ 16.19.20.41. PRESCRIPTIONS

A. A prescription for a controlled substance may be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice, and who is registered under the Controlled Substances Act. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

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16.19.29.6 NMAC

§ 16.19.29.6. OBJECTIVE

The objective of Part 29 of Chapter 19 is to promote the public health and welfare by detecting and preventing substance abuse and encouraging appropriate treatment of pain and other conditions for which controlled substances are prescribed. The purpose of the system is to improve access to controlled substances for legitimate medical needs by allowing a practitioner or a pharmacist to obtain a patient's pharmaceutical history related to controlled substances. The program's objectives will include education of the public and health care professionals regarding the nature and extent of the problem of drug abuse, appropriate prescribing and use of controlled substances, and the medical treatment options for abusers of controlled substances and pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (education) to provide practitioners information/education about pain management.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: "Excessive" implies there is a limit, but the limit is not specified.

16.10.8.8 NMAC

§ 16.10.8.8. UNPROFESSIONAL OR DISHONORABLE CONDUCT

As defined in the Medical Practice Act, Section 61-6-15,D,(29), "unprofessional or dishonorable conduct" includes, but is not limited to, the following:

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.
.

D. excessive prescribing or administering of drugs;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

16.10.14.1 – 16.10.14.9 NMAC

§ 16.10.14.1. ISSUING AGENCY

New Mexico Medical Board, hereafter called the board.

§ 16.10.14.2. SCOPE

This part applies to all physicians and physician assistants licensed by the board.

§ 16.10.14.3. STATUTORY AUTHORITY

These rules are promulgated pursuant to and in accordance with the Medical Practice Act, *sections 61-6-1 through 61-6-35 NMSA* 1978.

§ 16.10.14.4. DURATION

Permanent

§ 16.10.14.5. EFFECTIVE DATE

January 20, 2003, unless a later date is cited at the end of a section.

§ 16.10.14.6. OBJECTIVE

(+) *CRITERION 4: Encourages pain management*

It is the position of the board that practitioners have an obligation to treat chronic pain and that a wide variety of medicines including controlled substances and other drugs may be prescribed for that purpose. When such medicines and drugs are used, they should be prescribed in adequate doses and for appropriate lengths of time after a thorough medical evaluation has been completed.

§ 16.10.14.7. DEFINITIONS

A. "Addiction" is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects. It is characterized by behaviors that include one or more of the following: impaired control over drug use; compulsive use; continued use despite harm; and, craving. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not by themselves be considered addiction.

(+) *CRITERION 7: Physical dependence or analgesic tolerance are not confused with "addiction"*

B. "Chronic pain" means a pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated.

C. "Drug abuser" means a person who takes a drug or drugs for other than legitimate medical purposes.

D. "Pain" means an unpleasant sensory and emotional experience associated with inflammation or with actual or potential tissue damage, or described in terms of such inflammation and damage.

E. "Physical dependence" means a state of adaptation that is manifested by a drug-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, administration of an antagonist, or a combination of these.

F. "Tolerance" means a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

§ 16.10.14.8. GUIDELINES

The following guidelines will be used by the board to determine whether a physician's or physician assistant's prescriptive practices are consistent with the appropriate treatment of pain.

A. The treatment of pain with various medicines and/or controlled substances is a legitimate medical practice when accomplished in the usual course of professional practice. It does not preclude treatment of patients with addiction, physical dependence and/or tolerance who have legitimate pain. However, such patients do require very close monitoring and precise documentation.

B. The prescribing, ordering, administering or dispensing of controlled substances to meet the individual needs of the patient for management of chronic pain is appropriate if prescribed, ordered, administered or dispensed in compliance with the following.

(1) A practitioner shall complete a physical examination and include an evaluation of the patient's psychological and pain status. The medical history shall include any previous history of significant pain, past history of alternate treatments for pain, potential for substance abuse, coexisting disease or medical conditions, and the presence of a medical indication or contra-indication against the use of controlled substances.

(2) A written treatment plan shall be developed and tailored to the individual needs of the patient, taking age, gender, culture, and ethnicity into consideration, with stated objectives by which treatment can be evaluated, e.g. by degree of pain relief, improved physical and psychological function, or other accepted measure. Such a plan should include a statement of the need for further testing, consultation, referral or use of other treatment modalities.

(3) The practitioner shall discuss the risks and benefits of using controlled substances with the patient and/or surrogate or guardian.

(4) Complete and accurate records of care provided and drugs prescribed shall be maintained. When controlled substances are prescribed, the name of the drug, quantity, prescribed dosage and number of refills authorized should be recorded. Patients with a history of substance abuse or who are in an environment posing a high risk for misuse or diversion of drugs (e.g., living with a drug abuser, living or working in a place where drugs are available) may require special consideration.

(5) The management of patients needing chronic pain control requires monitoring by the attending and/or the consulting practitioner. In addition, a practitioner should consult, when indicated by the patient's condition, with health care professionals who are experienced (by the length and type of their practice) in the area of chronic pain control; such professionals need not be those who specialize in pain control. Consultation should occur early in the course of long-term treatment, and at reasonable intervals during continued long-term treatment for assessment of benefit and need. It is especially important, when treating addicts for legitimate pain apart from their addiction, to obtain a contractual agreement with the patient, appropriate consultation, and to set a schedule for re-evaluation at appropriate time intervals.

(6) If, in a practitioner's medical opinion, a patient is seeking pain medication for reasons that are not medically justified, the practitioner is not required to prescribe controlled substances for the patient.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEW MEXICO

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

C. The board will evaluate the quality of care on the following basis: appropriate diagnosis and evaluation; appropriate medical indication for the treatment prescribed; documented change or persistence of the recognized medical indication; and, follow-up evaluation with appropriate continuity of care. The board will judge the validity of prescribing based on the practitioner's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

D. The board will review both over-prescription and under-prescription of pain medications using the same standard of patient protection as a guiding principle.

E. A practitioner who appropriately prescribes controlled substances and who follows this section would be considered to be in compliance with this rule and not be subject to discipline by the board, unless there is some violation of the Medical Practice Act or board rules.

§ 16.10.14.9. PHYSICIAN, PHYSICIAN ASSISTANTS AND ANESTHESIOLOGIST ASSISTANTS TREATED WITH OPIATES

Physicians, physician assistants or anesthesiologist assistants who have chronic pain and are being treated with opiates shall be evaluated by a pain clinic or, by an M.D. or D.O. pain specialist, and must have a complete, independent neuropsychological evaluation, as well as clearance from their physician, before returning to or continuing in practice. In addition, they must remain under the care of a physician for as long as they remain on opiates while continuing in practice.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEW MEXICO

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Joint Statement on the Management of Chronic Pain

Pain management is a significant issue in health care today. Estimates of Americans experiencing pain range from 50-75 million persons annually. Thirty to fifty percent of patients undergoing cancer treatment experience pain. The effects of unmanaged pain are serious and wide-ranging and, yet, pain is widely under-treated. Untreated or inadequately treated pain impacts patients' quality of life and increases health care costs. Factors cited in the under-treatment of pain include concerns about causing addiction or tolerance; inadequate knowledge of controlled substances and pain management; fear of scrutiny and discipline by regulatory agencies; inadequate assessment; and patient reluctance to report pain or to take pain medications.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guidelines on pain management state, "Patients have the right to appropriate assessment and management of pain." (Emphasis added). It is, therefore, incumbent upon New Mexico physicians, nurses and pharmacists to work cooperatively and effectively to address the dimensions of pain and to provide maximum pain relief with minimal side effects. Towards that end, and in the interest of public protection, the New Mexico Boards of Medical Practice, Nursing and Pharmacy issue the following joint statement.

To effectively assist patients in the management of chronic pain, health care professionals should, within their scope of practice:

- Consistently and thoroughly assess all patients for pain. If the patient reports untreated or inadequately treated chronic pain, the pain should be evaluated with a complete history and physical with laboratory and diagnostic testing, if indicated;
- Work collaboratively in a multi-disciplinary approach to develop and implement an individualized, written treatment plan utilizing pharmacologic and non-pharmacologic interventions with specific objectives for the patient;
- Regularly evaluate the effectiveness of the treatment plan, using a consistent, developmentally appropriate, standardized pain scale, and make adjustments as needed;
- Document all aspects of pain assessment and care in a timely, clear, consistent, complete and accurate manner;
- Anticipate and effectively manage side effects of pain medications;
- Provide adequate and culturally appropriate information to patients and family members or caregivers to support patients in making informed decisions and participate in the management of their pain;
- Be aware of the risks of diversion and abuse of controlled substances and take appropriate steps to minimize there risks;
- Recognize individuals with chemical dependency may experience pain requiring medications, including opioids, and may require specialized management;
- Consult with, and refer patients to, other providers when appropriate;
- Develop organization-appropriate and evidence-based policies and protocols for pain management;
- Become and remain knowledgeable regarding effective pain management; and
- Comply with all state and federal laws and regulations regarding prescribing, dispensing, and administering legend drugs, including controlled substances.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes a practitioner's responsibility to provide patients information about pain management and palliative care when considering treatment plans.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pain Relief Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.M. Stat. Ann. § 24-2D-1 – § 24-2D-6

§ 24-2D-1. Short title

This act may be cited as the "Pain Relief Act".

§ 24-2D-2. Definitions

As used in the Pain Relief Act [*24-2D-1 NMSA* 1978]:

A. "accepted guideline" means a care or practice guideline for pain management developed by a national joint commission on accreditation of health care organizations; the American pain society; an American geriatrics society; the agency for health care research and quality; a national cancer pain initiative or any other nationally recognized clinical or professional association; or a specialty society or government-sponsored agency that has developed practice or care guidelines based on original research or on review of existing research and expert opinion whose guidelines have been accepted by the New Mexico medical board and by other boards of health care providers with prescriptive authority;

B. "board" means the licensing board of a health care provider;

C. "clinical expert" means a person who by reason of specialized education or substantial relevant experience in pain management has knowledge regarding current standards, practices and guidelines;

D. "disciplinary action" means a formal action taken by a board against a health care provider, upon a finding of probable cause that the health care provider has engaged in conduct that violates the provider's respective board's practice act;

E. "health care provider" means a person licensed or otherwise authorized by law to provide health care in the ordinary course of business or practice of the person's profession and to have prescriptive authority within the limits of the person's license;

F. "pain" means a condition of bodily sensation of serious physical discomfort that requires the services of a health care provider to alleviate, including discomfort that is persistent and chronic in duration; and

G. "therapeutic purpose" means the use of pharmaceutical and non-pharmaceutical medical treatment that conforms substantially to accepted guidelines for pain management.

§ 24-2D-3. Disciplinary action; evidentiary requirements

A. A health care provider who prescribes, dispenses or administers medical treatment for the purpose of relieving pain and who can demonstrate by reference to an accepted guideline that the provider's practice substantially complies with that guideline and with the standards of practice identified in *Section 24-2D-4 NMSA* 1978 shall not be disciplined pursuant to board action or criminal prosecution, unless the showing of substantial compliance with an accepted guideline by the health care provider is rebutted by clinical expert testimony. If no currently accepted guidelines are available, then rules issued by the board may serve the function of such guidelines for purposes of the Pain Relief Act [*24-2D-1 NMSA* 1978]. The board rules shall conform to the intent of that act. Guidelines established primarily for purposes of coverage, payment or reimbursement do not qualify as an "accepted guideline" when offered to limit treatment options otherwise covered within the Pain Relief Act.

B. In the event that a disciplinary action or criminal prosecution is pursued, the board or prosecutor shall produce clinical expert testimony supporting the finding or charge of violation of disciplinary standards or other legal requirements on the part of the health care provider. A showing of substantial compliance with an accepted guideline shall only be rebutted by clinical expert testimony.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Identifies the possibility of reimbursement as an important barrier to the appropriate use of opioids analgesics.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (immunity) to protect physicians treating intractable pain from criminal prosecution.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEW MEXICO

STATUTES

Pain Relief Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not contraindicate appropriate pain management.

(CONTINUED)

C. The provisions of this section apply to health care providers in the treatment of pain, regardless of a patient's prior or current chemical dependency or addiction. Each board shall adopt rules establishing standards and procedures for the application of the Pain Relief Act [*24-2D-1 NMSA* 1978], including the care and treatment of chemically dependent individuals.

D. In an action brought by a board against a health care provider based on treatment of a patient for pain, the board shall consider the totality of the circumstances and shall not use as the sole basis of the action:

(1) a patient's age;

(2) a patient's diagnosis;

(3) a patient's prognosis;

(4) a patient's history of drug abuse;

(5) the absence of consultation with a pain specialist; or

(6) the quantity of medication prescribed or dispensed.

§ 24-2D-4. Disciplinary action; prohibitions

Nothing in the Pain Relief Act [*24-2D-1 NMSA* 1978] shall prohibit discipline or prosecution of a health care provider for:

A. failing to maintain complete, accurate and current records documenting the physical examination and medical history of the patient, the basis for the clinical diagnosis of the patient and the treatment plan for the patient;

B. writing false or fictitious prescriptions for controlled substances scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970 or *Sections 26-1-23* and *30-31-18 NMSA* 1978;

C. prescribing, administering or dispensing pharmaceuticals in violation of the provisions of the federal Comprehensive Drug Abuse Prevention and Control Act of 1970 or *Sections 26-1-23* and *30-31-18 NMSA* 1978; or

D. diverting medications prescribed for a patient to the provider's personal use or to other persons.

§ 24-2D-5. Notification

The board shall make reasonable efforts to notify health care providers under its jurisdiction of the existence of the Pain Relief Act [*24-2D-1 NMSA* 1978] and inform any health care provider investigated in relation to the provider's practices in the management of pain of the existence of that act.

§ 24-2D-5.1. Pain management continuing education

A board shall encourage pain management continuing education for all health care providers who have prescriptive authority and who treat patients with pain.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (adopting rules) to establish standards and procedures for the appropriate treatment of patients with pain.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to communicate to practitioners about acceptable practices governing pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (encouraging continuing education) to provide practitioners information/education about pain management and palliative care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pain Relief Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (advisory council) to improve pain management.

(CONTINUED)

§ 24-2D-5.2. Pain management advisory council created; duties

A. The "pain management advisory council" is created and shall be administratively attached to the department of health. Members of the council shall be appointed by the governor to consist of one representative each from the New Mexico medical board, the board of nursing, the board of pharmacy, the board of osteopathic medical examiners, the board of acupuncture and oriental medicine, the university of New Mexico health sciences center, a statewide medical association, a statewide association of pharmacists, a statewide association of nurse practitioners, a statewide association of certified registered nurse anesthetists and a statewide association of osteopathic physicians; one person who is a consumer health care advocate; and three persons who have no direct ties or pecuniary interest in the health care fields.

B. The council shall meet at least quarterly to review current pain management practices in New Mexico and national pain management standards and educational efforts for both consumers and professionals and shall recommend pain management guidelines for each health care profession licensed in New Mexico with prescriptive authority to its respective board. Members who are not public employees shall receive per diem and mileage as provided in the Per Diem and Mileage Act [*10-8-1 NMSA* 1978]. Public employee members shall receive mileage from their respective employers for attendance at council meetings.

§ 24-2D-6. Scope of act

Nothing in the Pain Relief Act [*24-2D-1 NMSA* 1978] shall be construed as expanding the authorized scope of practice of health care providers.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Opioid Treatment Programs

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for OTP staff to refer methadone-maintained patients who have chronic pain for treatment of their pain

7.32.8.26 NMAC

§ 7.32.8.26. DIVERSE POPULATIONS

A. The program sponsor shall ensure that:

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(9) an individual who requires administration of opioid treatment medication only for relief of chronic pain is:

(a) identified during the physical examination or assessment;

(b) not admitted for opioid medication treatment; and

(c) referred for medical services; and

(d) for a patient with a chronic pain disorder who is also physically dependent the OTP makes a good faith effort to coordinate treatment and services with the medical practitioner treating the patient for pain management.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NY

NEW YORK

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Public Health Law; Article 33. Controlled Substances

- MEDICAL PRACTICE ACT
  Public Health Law; Article 2-A. The Department of Health; Title II-A. Professional Medical Conduct

  Education Law; Title VIII. The Professions; Article 131. Medicine

- PHARMACY PRACTICE ACT (*No provisions found*)
  Education Law; Title VIII. The Professions; Article 137. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 10. Department of Health; Chapter II. Administrative Rules and Regulations; Subchapter K. Controlled Substances; Part 80. Rules and Regulations on Controlled Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 8. Education Department; Chapter II. Regulations of the Commissioner; Subchapter B. Regulation of Professions; Part 60. Medicine, Physician's Assistant, Specialist's Assistant and Acupuncture

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 8. Education Department; Chapter II. Regulations of the Commissioner; Subchapter B. Regulation of Professions; Part 63. Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  Board of Professional Medical Conduct. *Pain Management: A Guide for Physicians*. Approved: August, 2007.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- FACILITIES
  Unconsolidated Laws; Public Health; Chapter 214-A. New York City Health and Hospitals Corporation

- HOSPITALS
  Public Health Law; Article 28. Hospitals

- NURSING HOME STANDARDS
  Title 10. Department of Health; Chapter V. Medical Facilities; Subchapter A. Medical Facilities – Minimum Standards; Article 3. Residential Care Facilities

- HOSPICE OPERATION
  Title 10. Department of Health; Chapter V. Medical Facilities; Subchapter C. State Hospital Code; Article 9. Hospice Operation

NY

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					●
Medical Practice Act		●						
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					●
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Facilities		●						
Hospitals								●
Nursing Home Standards								●
Hospice Operation								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act				●		●		
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances				●		●		●
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Facilities[1]								
Hospitals[1]								
Nursing Home Standards[1]								
Hospice Operation[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

NY CLS Pub Health § 3300-a

§ 3300-a. Legislative purposes

The purposes of this article are:

1. to combat illegal use of and trade in controlled substances; and

2. to allow legitimate use of controlled substances in health care, including palliative care; veterinary care; research and other uses authorized by this article or other law; under appropriate regulation and subject to this article, title eight of the education law, and other applicable law.

NY CLS Pub Health § 3302

§ 3302. Definitions of terms of general use in this article

Except where different meanings are expressly specified in subsequent provisions of this article, the following terms have the following meanings:

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(+) *CRITERION 3:*
Opioids are part of professional practice

29. "Practitioner" means:
A physician, dentist, podiatrist, veterinarian, scientific investigator, or other person licensed, or otherwise permitted to dispense, administer or conduct research with respect to a controlled substance in the course of a licensed professional practice or research licensed pursuant to this article. Such person shall be deemed a "practitioner" only as to such substances, or conduct relating to such substances, as is permitted by his license, permit or otherwise permitted by law.

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NY CLS Pub Health § 3331

§ 3331. Scheduled substances administering and dispensing by practitioners

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5. No more than a thirty day supply or, pursuant to regulations of the commissioner enumerating conditions warranting specified greater supplies, no more than a three month supply of a schedule II, III or IV substance, as determined by the directed dosage and frequency of dosage, may be dispensed by an authorized practitioner at one time.

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(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY C:
Restrictions regarding quantity prescribed or dispensed

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

NEW YORK

NY CLS Pub Health § 3332 - § 3333

§ 3332. Making of official New York state prescriptions for scheduled substances

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3. No such prescription shall be made for a quantity of controlled substances which would exceed a thirty day supply if the controlled substance were used in accordance with the directions for use specified on the prescription. A practitioner may, however, issue a prescription for up to a three month supply of a controlled substance provided that the controlled substance has been prescribed to treat one of the conditions that have been enumerated by the commissioner pursuant to regulations as warranting the prescribing of greater than a thirty day supply of a controlled substance and that the practitioner specifies the condition on the face of the prescription. No additional prescriptions for a controlled substance may be issued by a practitioner to an ultimate user within thirty days of the date of any prescription previously issued unless and until the ultimate user has exhausted all but a seven day supply of the controlled substance provided by any previously issued prescription. A practitioner may, however, issue a prescription for up to a six month supply of any substance listed in subdivision (h) [fig 1] of Schedule II of section three thousand three hundred six of this article provided that such substance has been prescribed to treat one of the conditions that have been enumerated by the commissioner pursuant to regulations as warranting the prescribing of a six month supply and that the practitioner specifies the condition on the face of the prescription.

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§ 3333. Dispensing upon official New York state prescription

1. A licensed pharmacist may, in good faith and in the course of his or her professional practice, sell and dispense to an ultimate user controlled substances for which an official New York state prescription is required only upon the delivery to such pharmacist, within thirty days of the date such prescription was signed by an authorized practitioner, of the original and one copy of such official New York state prescription; provided, however, a pharmacist may dispense a part or portion of such prescription in accordance with regulations of the commissioner. No pharmacy or pharmacist may sell or dispense greater than a thirty day supply of a controlled substance to an ultimate user unless and until the ultimate user has exhausted all but a seven day supply of the controlled substance provided pursuant to any previously issued official New York state prescription, except that a pharmacy or pharmacist may sell or dispense up to a three month supply of a controlled substance if there appears, on the face of the official New York state prescription, a statement that the controlled substance has been prescribed to treat one of the conditions that have been enumerated by the regulations of the commissioner as warranting the prescribing of greater than a thirty day supply of a controlled substance.

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NY CLS Pub Health § 3350

§ 3350. Dispensing prohibition

Controlled substances may not be prescribed for, or administered or dispensed to addicts or habitual users of controlled substances, except as provided by this title or title III.

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NY CLS Pub Health § 3351

§ 3351. Dispensing for medical use

1. Controlled substances may be prescribed for, or administered or dispensed to an addict or habitual user:
(a) during emergency medical treatment unrelated to abuse of controlled substances;
(b) who is a bona fide patient suffering from an incurable and fatal disease such as cancer or advanced tuberculosis;
(c) who is aged, infirm, or suffering from serious injury or illness and the withdrawal from controlled substances would endanger the life or impede or inhibit the recovery of such person.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exemption of these patients from special prescription requirements nevertheless continues those requirements for all other patients.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exemption of these patients nevertheless continues the prescribing restriction for all other patients with an addictive disease or history of addiction.

(-) *CRITERION 14:*
Undue prescription requirements

COMMENT: Strict enforcement of such a provision could be a burden to the physician and the patient. This provision could necessitate that the physician confirm the supply of the medication remaining for every patient.

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

NY CLS Educ § 6521

§ 6521. Definition of practice of medicine

The practice of the profession of medicine is defined as diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEW YORK

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

10 NYCRR § 80.62

§ 80.62 Use of controlled substances in treatment.

(a) Physicians and other authorized practitioners in the course of their professional practice, may dispense, administer or prescribe controlled substances for legitimate medical purposes or treatment, other than treatment for addiction to controlled substances, when the practitioner regulates the dosage and prescribes or administers a quantity of such drugs no greater than that ordinarily recognized by members of his profession as sufficient for proper treatment in a given case.

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10 NYCRR § 80.67

§ 80.67 Schedule II and certain other substances

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(c) Except as provided for in subdivision (d) of this section, no such prescription shall be made for a quantity of substances which would exceed a 30-day supply if the substance were used in accordance with the directions for use, specified on the prescription. No additional prescriptions for a controlled substance may be issued by a practitioner to an ultimate user within 30 days of the date of any prescription previously issued unless and until the ultimate user has exhausted all but a seven days' supply of that controlled substance provided by any previously issued prescription.

(d) (1) A practitioner may issue a prescription for up to a three month supply of a controlled substance or up to a six month supply of an anabolic steroid or chorionic gonadotrophin if used in accordance with the direction for use, provided that the controlled substance has been prescribed for the treatment of:

(i) attention deficit disorder;

(ii) chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive or spasm activity;

(iii) relief of pain in patients suffering from diseases known to be chronic and incurable;

(iv) narcolepsy;

(v) panic disorders; or

(vi) hormone deficiency states in males, gynecologic conditions that are responsive to treatment with anabolic steroids or chorionic gonadotrophin, metastatic breast cancer in women, anemia and angioedema.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 12:*
Medical decisions are restricted

***CATEGORY C*:**
Restrictions regarding quantity prescribed or dispensed

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: The exemption of these patients from special prescription requirements nevertheless continues those requirements for all other patients. Although pain patients with chronic and incurable diseases are able to receive prescriptions for three months, this may not cover patients with chronic pain from a curable disease.

(-) *CRITERION 16:*
Provisions that are ambiguous

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: Although professional practice in pain management is improving, it may be inappropriate to rely on such a standard given the widespread inadequate management of pain.

(-) *CRITERION 14:*
Undue prescription requirements

COMMENT: Strict enforcement of such a provision could be a burden to the physician and the patient. This provision could necessitate that the physician confirm the supply of the medication remaining for every patient.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEW YORK

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

10 NYCRR § 80.76

§ 80.76 Dispensing; prohibition

Controlled substances shall not be prescribed for, administered or dispensed to addicts or habitual users of controlled substances except as provided by the Public Health Law or this Part.

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§ 80.85 Administration of controlled substances to addicts and habitual users

(a) The administration of controlled substances to narcotic addicts or habitual users of controlled substances is prohibited except as provided for in this Part.

(b) Controlled substances may be administered to narcotic addicts or habitual users of controlled substances upon the order of a person authorized by law to practice medicine or osteopathy in this State and who possesses a Federal registration by the Drug Enforcement Administration, United States Department of Justice, authorizing him to use controlled substances in connection with his professional practice as follows:

(1) for bona fide patients suffering from disease known to be incurable, such as cancer, advanced tuberculosis, and other diseases well recognized as coming within this class;

(2) for addicts who are aged and infirm, or severely ill and it is determined that withdrawal of controlled substances would be dangerous to life, provided that:

(i) such determination has been confirmed by adequate consultation;

(ii) complete records of treatment, administration or dispensing of controlled substances including patient's name, date and type and quantity of controlled substance administered or dispensed are kept;

(iii) adequate safeguards have been taken against diversion of the controlled substances from the intended use; and

(iv) the patient is carefully supervised;

(3) to relieve acute withdrawal symptoms, except that:

(i) only the amount of controlled substances essential for relief of such acute symptoms shall be administered; and

(ii) administration shall be in an institutional or other setting reasonably certain to provide a drug-free environment;

(4) for detoxification of an addict participating in an authorized treatment program approved pursuant to article 23 of the Mental Hygiene Law; and

(5) for treatment of addicts participating in an authorized methadone or other controlled substances maintenance program approved pursuant to article 23 of the Mental Hygiene Law.

(c) In properly verified cases of severe illness, infirmity, or physical disability, a licensed physician, registered nurse, licensed practical nurse, or registered pharmacist may deliver medication to the patient.

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY B:
Mandated consultation

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY C:
Conflicting or inconsistent policies or provisions

COMMENT: Patients who are addicts or habitual users, and who meet these standards, are exempt from the prescribing restriction of §80.76. However, the language in §80.85(b,2), which uses the phrase "aged and infirm, or severely ill," differs from the language in the Controlled Substances Act §3351(c), which uses the phrase "aged, infirm, or suffering," thereby appearing to establish two separate standards.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exemption of these patients nevertheless continues the prescribing restriction for all other patients with an addictive disease or history of addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

PAIN MANAGEMENT: A GUIDE FOR PHYSICIANS

INTRODUCTION

The New York State Board for Professional Medical Conduct (Board) recognizes that principles of quality medical practice dictate that the people of the State of New York have access to appropriate and effective pain relief. Inadequate pain control may result from physician[1] lack of knowledge about pain management, inadequate understanding of addiction, or fear of investigation or action by the Board or other federal, state or local regulatory agencies. This publication therefore has been developed to clarify the Board's position on pain control, to encourage better pain management and to dispel physician fears of unwarranted legal consequences.

The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain, as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The complexity of pain management often requires intradisciplinary consultation.

The Board encourages and expects physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, including pain as a result of terminal illness.

All physicians should become knowledgeable about effective methods of pain evaluation and treatment, as well as statutory requirements for prescribing controlled substances.

CONTROLLED SUBSTANCES

The Board recognizes that controlled substances, including opioid analgesics, are often essential in the treatment of acute and chronic pain (both malignant and nonmalignant). If the treatments are based on accepted medical practices and sound clinical grounds, the Board considers prescribing, administering or dispensing controlled substances for pain to be legitimate. The Board also recognizes that tolerance and physical dependency may be pharmacological effects of sustained use of opioid analgesics and are not synonymous with addiction.

Pursuant to the laws of the State of New York, the Board is bound to protect the public health and safety. Inappropriate prescribing of controlled substances may lead to drug diversion and abuse by individuals who seek drugs for other than legitimate medical use. Therefore, physicians should be aware that the Board will not tolerate the diversion of drugs for illegitimate purposes.

POINTS OF INFORMATION

- An adequate assessment of the patient and the pain should be performed and documented.
- Pain should be considered a fifth vital sign that is viewed as a fundamental assessment of well-being, and which is regularly monitored.
- Communication is essential. Many patients, for various reasons, are unable to describe adequately their pain. Physicians should initiate conversations to identify pain and qualify/quantify it and its impact on the patient's life.
- Treatment should be based on the diagnosis, type of pain, intensity and duration of pain, prior therapies, and the impact on quality of life.
- Ongoing evaluation of pain, patient compliance, and treatment efficacy should be performed and documented.
- The definition of **addict** under the Controlled Substance Law excludes patients using controlled substances for legitimate medical purposes. The term **addiction** refers to compulsive use of controlled substances for non-legitimate purposes and is associated with loss of control and use despite harm. Many patients are reluctant to seek pain relief because of the fear of addiction. Clarification from their physicians is essential.
- Certain patients with pain, such as those with history of substance abuse or comorbid psychiatric disorder, may require extra attention, monitoring, documentation and consultation.
- The Board evaluates **inappropriate** versus **appropriate** prescribing, not the quantity of drugs prescribed. The Bureau of Narcotic Enforcement has reviewed and concurs with these guidelines.

1 For the purposes of this document, the term physicians shall refer to physicians, medical residents, physician assistants and specialist assistants.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

NEW YORK

STATUTES

Facilities

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

NY CLS Unconsol Ch 214-A, § 3

§ 3. Definitions

As used or referred to in this act, unless a different meaning clearly appears from the text:

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13. "Health and medical services" shall mean items or services provided by or under the supervision of a physician or other person trained or licensed to render health care necessary for the prevention, care, diagnosis or treatment of human disease, pain, injury, deformity or other physical or mental condition including, but not limited to, pre-admission, out-patient, in-patient and post-discharge care, home care, physicians' care, nursing care, medical care provided by interns or residents-in-training and other paramedical care, ambulance service, bed and board, drugs, biologicals, supplies, appliances, equipment, laboratory services and x-ray, radium and radio-active-isotope therapy.

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STATUTES

Hospitals

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

NY CLS Pub Health § 2800

§ 2800. Declaration of policy and statement of purpose

Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of the article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that pain management is an essential part of hospital care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NEW YORK

REGULATIONS

Nursing Homes

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

10 NYCRR § 415.26

§ 415.26 ADMINISTRATIVE 415.26 Organization and administration

A nursing home shall be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

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(i) The nurse aide training program shall include classroom and clinical training which enhances both skills and knowledge and, when combined, shall be of at least 100 hours' duration. The clinical training shall as a minimum include at least 30 hours of supervised practical experience in a nursing home. The nurse aide training program shall include stated goals, objectives, and measurable performance criteria specific to the curriculum subject material, the resident population and the purpose of the facility, and shall be consistent with the curriculum outlined below. This curriculum shall be taught at a fourth to sixth grade English literacy level. Facilities with special populations shall supplement the curriculum to address the needs of such populations accordingly. The curriculum shall otherwise include, but not be limited to the following:

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(n) nursing care needs of resident with special needs due to medical conditions such as but not limited to:

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(6) pain management;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (training program) for nursing homes to ensure that pain management is an essential part of patient care.

REGULATIONS

Hospice Operation

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that pain management is an essential part of hospice care.

10 NYCRR § 794.4

§ 794.4 Hospice inpatient and residence services

(a) Part 702 of this Title and Part 14 of the Sanitary Code shall apply to all hospice inpatient settings and hospice residence settings, as applicable.

(b) The hospice may provide short-term inpatient services for pain control and management of symptoms related to the terminal illness in a free-standing hospice facility, a skilled nursing facility or a general hospital.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NC

NORTH CAROLINA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Chapter 90. Medicine and Allied Occupations;
  Article 5. North Carolina Controlled Substances Act
  Article 5E. North Carolina Controlled Substances Reporting System Act (*No provisions found*)

- MEDICAL PRACTICE ACT
  Chapter 90. Medicine and Allied Occupations; Article 1. Practice of Medicine

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Chapter 90. Medicine and Allied Occupations; Article 7. Osteopathy

- PHARMACY PRACTICE ACT (*No provisions found*)
  Chapter 90. Medicine and Allied Occupations; Article 4A. North Carolina Pharmacy Practice Act

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 10A. Department of Health and Human Services; Chapter 26. Mental Health: General; Subchapter
  26E. Manufacturers: Distributors: Dispensers and Researchers of Controlled Substances
  26F. Controlled Substances

- MEDICAL BOARD REGULATIONS
  Title 21. Occupational Licensing Boards; Chapter 32. Board of Medical Examiners

- OSTEOPATHIC BOARD REGULATIONS (*Repealed*)
  Title 21. Occupational Licensing Boards; Chapter 44. Board of Osteopathic Examination and Registration

- PHARMACY BOARD REGULATIONS
  Title 21. Occupational Licensing Boards; Chapter 46. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  North Carolina Medical Board. *Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: July 2005.

- MEDICAL BOARD POLICY STATEMENT
  North Carolina Board of Medical Examiners. *End-of-Life Responsibilities and Palliative Care*. Adopted: October 21, 1999.

- JOINT BOARD POLICY STATEMENT
  North Carolina Medical, Nursing, and Pharmacy Boards. *Joint Statement on Pain Management in End-of-Life Care*. Adopted: October 21, 1999.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- FOOD, DRUGS AND COSMETICS
  Chapter 106. Agriculture; Article 12. Food, Drugs and Cosmetics

NC

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					●
Medical Practice Act		●						
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					
Medical Board			●					
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement		●	●	●	●	●	●	●
Medical Board Policy Statement				●	●			●
Joint Board Policy Statement				●	●			●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Food, Drugs and Cosmetics			●					

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act			●			●		
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board							●	
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement[1]								
Medical Board Policy Statement[1]								
Pharmacy Board Policy Statement[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Food, Drugs and Cosmetics[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

NORTH CAROLINA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.C. Gen. Stat. § 90-87

§ 90-87. Definitions

As used in this Article:

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(13) "Drug dependent person" means a person who is using a controlled substance and who is in a state of psychic or physical dependence, or both, arising from use of that controlled substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects, or to avoid the discomfort of its absence.

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(22) "Practitioner" means:

a. A physician, dentist, optometrist, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance so long as such activity is within the normal course of professional practice or research in this State.

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N.C. Gen. Stat. § 90-109.1

§ 90-109.1. Treatment

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. (c) Every practitioner that provides treatment or rehabilitation services to a person dependent upon drugs shall periodically as required by the Secretary of the North Carolina Department of Health and Human Services commencing January 1, 1972, make a statistical report to the Secretary of the North Carolina Department of Health and Human Services in such form and manner as the Secretary shall prescribe for each such person treated or to whom rehabilitation services were provided. The form of the report prescribed shall be furnished by the Secretary of the North Carolina Department of Health and Human Services. Such report shall include the number of persons treated or to whom rehabilitation services were provided; the county of such person's legal residence; the age of such person; the number of such persons treated as inpatients and the number treated as outpatients; the number treated who had received previous treatment or rehabilitation services; and any other data required by the Secretary. If treatment or rehabilitation services are provided to a person by a hospital, public agency, or drug treatment facility, such hospital, public agency, or drug treatment facility shall coordinate with the treating medical practitioner so that statistical reports required in this section shall not duplicate one another. The Secretary shall cause all such reports to be compiled into periodical reports which shall be a public record.

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N.C. Gen. Stat. § 90-113.71

§ 90-113.71. Legislative findings and purpose

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(b) This Article is intended to improve the State's ability to identify controlled substance abusers or misusers and refer them for treatment, and to identify and stop diversion of prescription drugs in an efficient and cost-effective manner that will not impede the appropriate medical utilization of licit controlled substances.

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(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 14:*
Practitioners are subject to undue prescription requirements

COMMENT: Requires practitioners to submit reports of all patients considered drug dependent, which the Secretary of the North Carolina Department of Health and Human Services will compile into a public record. The state legal definition of drug dependence could include patients with pain who are physically dependent as a result of opioid treatment.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.C. Gen. Stat. § 90-1.1

§ 90-1.1. Definitions

The following definitions apply in this Article:

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(5) The practice of medicine or surgery. -- The practice of medicine or surgery, for purposes of this Article, includes any of the following acts:

a. Advertising, holding out to the public, or representing in any manner that the individual is authorized to practice medicine in this State.

b. Offering or undertaking to prescribe, order, give, or administer any drug or medicine for the use of any other individual.

c. Offering or undertaking to prevent or diagnose, correct, prescribe for, administer to, or treat in any manner or by any means, methods, or devices any disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of any individual, including the management of pregnancy or parturition.

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(+) *CRITERION 2:*
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NORTH CAROLINA

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

10A N.C.A.C. 26E.0102

.0102 DEFINITIONS

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(10) The term "individual practitioner" means same as defined in *G.S. 90-87* (by reference: A physician, dentist, optometrist, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance so long as such activity is within the normal course of professional practice or research in this State.)

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(+) *CRITERION 3:*
Opioids are part of professional practice

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

21 N.C.A.C. 32B.1001

.1001 AUTHORITY TO PRESCRIBE

(a) A license to practice medicine issued under this Subchapter allows the physician to prescribe medications, including controlled substances, so long as the physician complies with all state and federal laws and regulations governing the writing and issuance of prescriptions.

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REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 15:*
Other provisions that may impede pain management

COMMENT: Could become a barrier if the pharmacist determined potential harm based solely on the quantity of the prescription.

21 N.C.A.C. 46.1801

.1801 RIGHT TO REFUSE A PRESCRIPTION

(a) A pharmacist or device and medical equipment dispenser may refuse to fill or refill a prescription order, if, in his professional judgment, it would be harmful to the recipient, is not in the recipient's best interest or if there is a question as to its validity.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Policy for the Use of Controlled Substances for the Treatment of Pain

- Appropriate treatment of chronic pain may include both pharmacologic and non-pharmacologic modalities. The Board realizes that controlled substances, including opioid analgesics, may be an essential part of the treatment regimen.
- All prescribing of controlled substances must comply with applicable state and federal law.
- Guidelines for treatment include: (a) complete patient evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.
- Deviation from these guidelines will be considered on an individual basis for appropriateness.

Section I: Preamble

The North Carolina Medical Board recognizes that principles of quality medical practice dictate that the people of the State of North Carolina have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practice might be.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

The North Carolina Medical Board is obligated under the laws of the State of North Carolina to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient —A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan —The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

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(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Informed Consent and Agreement for Treatment —The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills;
- and reasons for which drug therapy may be discontinued (e.g., violation of agreement).

Periodic Review —The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation —The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records —The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

6. informed consent,

7. treatments,

8. medications (including date, type, dosage and quantity prescribed),

9. instructions and agreements and

10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations —To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and any relevant documents issued by the state of North Carolina for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain —Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction —Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain —Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain —An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence —Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Pseudoaddiction —The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse —Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance —Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

END-OF-LIFE RESPONSIBILITIES AND PALLIATIVE CARE

Assuring Patients

Death is part of life. When appropriate processes have determined that the use of life-sustaining or invasive interventions will only prolong the dying process, it is incumbent on physicians to accept death "not as a failure, but the natural culmination of our lives."*

It is the position of the North Carolina Medical Board that patients and their families should be assured of competent, comprehensive palliative care at the end of their lives. Physicians should be knowledgeable regarding effective and compassionate pain relief, and patients and their families should be assured such relief will be provided.

Palliative Care

There is no one definition of palliative care, but the Board accepts that found in the *Oxford Textbook of Palliative Medicine*: "The study and management of patients with active, progressive, far advanced disease for whom the prognosis is limited and the focus of care is the quality of life." This is not intended to exclude remissions and requires that the management of patients be comprehensive, embracing the efforts of medical clinicians and of those who provide psychosocial services, spiritual support, and hospice care.

A physician who provides palliative care, encompassing the full range of comfort care, should assess his or her patient's physical, psychological, and spiritual conditions. Because of the overwhelming concern of patients about pain relief, special attention should be given the effective assessment of pain. It is particularly important that the physician frankly but sensitively discuss with the patient and the family their concerns and choices at the end of life. As part of this discussion, the physician should make clear that, in some cases, there are inherent risks associated with effective pain relief in such situations.

Opioid Use

The Board will assume opioid use in such patients is appropriate if the responsible physician is familiar with and abides by acceptable medical guidelines regarding such use, is knowledgeable about effective and compassionate pain relief, and maintains an appropriate medical record that details a pain management plan. (See the Board's position statement on the Management of Chronic Non-Malignant Pain for an outline of what the Board expects of physicians in the management of pain.) Because the Board is aware of the inherent risks associated with effective pain relief in such situations, it will not interpret their occurrence as subject to discipline by the Board.

Selected Guides

To assist physicians in meeting these responsibilities, the Board recommends *Cancer Pain Relief: With a Guide to Opioid Availability*, 2nd ed (1996), *Cancer Pain Relief and Palliative Care* (1990), *Cancer Pain Relief and Palliative Care in Children* (1999), and *Symptom Relief in Terminal Illness* (1998), (World Health Organization, Geneva); *Management of Cancer Pain* (1994), (Agency for Health Care Policy and Research, Rockville, MD); *Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain*, 4th Edition (1999) (American Pain Society, Glenview, IL); *Hospice Care: A Physician's Guide* (1998) (Hospice for the Carolinas, Raleigh); and the *Oxford Textbook of Palliative Medicine* (1993) (Oxford Medical, Oxford).

(+) *CRITERION 4:* *Encourages pain management*

(+) *CRITERION 8:* *Other provisions that may enhance pain management*

CATEGORY A: ***Issues related to healthcare professionals***

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 5:* *Addresses fear of regulatory scrutiny*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

JOINT STATEMENT ON PAIN MANAGEMENT
IN END-OF-LIFE CARE

Through dialogue with members of the healthcare community and consumers, a number of perceived regulatory barriers to adequate pain management in end-of-life care have been expressed to the Boards of Medicine, Nursing, and Pharmacy. The following statement attempts to address these misperceptions by outlining practice expectations for physicians and other health care professionals authorized to prescribe medications, as well as nurses and pharmacists involved in this aspect of end-of-life care. The statement is based on:

the legal scope of practice for each of these licensed health professionals;

professional collaboration and communication among health professionals providing palliative care; and

a standard of care that assures on-going pain assessment, a therapeutic plan for pain management interventions; and evidence of adequate symptom management for the dying patient.

(+) *CRITERION 4:* *Encourages pain management*

It is the position of all three Boards that patients and their families should be assured of competent, comprehensive palliative care at the end of their lives. Physicians, nurses and pharmacists should be knowledgeable regarding effective and compassionate pain relief, and patients and their families should be assured such relief will be provided.

Because of the overwhelming concern of patients about pain relief, the physician needs to give special attention to the effective assessment of pain. It is particularly important that the physician frankly but sensitively discuss with the patient and the family their concerns and choices at the end of life. As part of this discussion, the physician should make clear that, in some end of life care situations, there are inherent risks associated with effective pain relief. *The Medical Board will assume opioid use in such patients is appropriate if the responsible physician is familiar with and abides by acceptable medical guidelines regarding such use, is knowledgeable about effective and compassionate pain relief, and maintains an appropriate medical record that details a pain management plan.* Because the Board is aware of the inherent risks associated with effective pain relief in such situations, it will not interpret their occurrence as subject to discipline by the Board.

(+) *CRITERION 5:* *Addresses fear of regulatory scrutiny*

With regard to pharmacy practice, North Carolina has no quantity restrictions on dispensing controlled substances including those in Schedule II. This is significant when utilizing the federal rule that allows the partial filling of' Schedule II prescriptions for up to 60 days. In these situations it would minimize expenses and unnecessary waste of drugs if the prescriber would note on the prescription that the patient is terminally ill and specify the largest anticipated quantity that could be needed for the next two months. The pharmacist could then dispense smaller quantities of the prescription to meet the patient's needs up to the total quantity authorized. Government-approved labeling for dosage level and frequency can be useful as guidance for patient care. Health professionals may, on occasion, determine that higher levels are justified in specific cases. However, these occasions would be exceptions to general practice and would need to be properly documented to establish informed consent of the patient and family.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Federal and state rules also allow the fax transmittal of an original prescription for Schedule II drugs for hospice patients. If the prescriber notes the hospice status of the patient on the faxed document, it serves as the original. Pharmacy rules also allow the emergency refilling of prescriptions in Schedules III, IV, and V. While this does not apply to Schedule II drugs, it can be useful in situations where the patient is using drugs such as Vicodin for pain or Xanax for anxiety.

The nurse is often the health professional most involved in on-going pain assessment, implementing the prescribed pain management plan, evaluating the patient's response to such interventions and adjusting medication levels based on patient status. In order to achieve adequate pain management, the prescription must provide dosage ranges and frequency parameters within which the nurse may adjust (titrate) medication in order to achieve adequate pain control. Consistent with the licensee's scope of practice, the RN or LPN is accountable for implementing the pain management plan utilizing his/her knowledge base and documented assessment of the patient's needs. *The nurse has the authority to adjust medication levels within the dosage and frequency ranges stipulated by the prescriber and according to the agency's established protocols.* However, the nurse does not have the authority to change the medical pain management plan. When adequate pain management is not achieved under the currently prescribed treatment plan, the nurse is responsible for reporting such findings to the prescriber and documenting this communication. Only the physician or other health professional with authority to prescribe may change the medical pain management plan.

Communication and collaboration between members of the healthcare team, and the patient and family are essential in achieving adequate pain management in end-of-life care. Within this interdisciplinary framework for end of life care, effective pain management should include:

- thorough documentation of all aspects of the patient's assessment and care;
- a working diagnosis and therapeutic treatment plan including pharmacologic and non-pharmacologic interventions;
- regular and documented evaluation of response to the interventions and, as appropriate, revisions to the treatment plan;
- evidence of communication among care providers;
- education of the patient and family; and
- a clear understanding by the patient, the family and healthcare team of the treatment goals.

It is important to remind health professionals that licensing boards hold each licensee accountable for providing safe, effective care. Exercising this standard of care requires the application of knowledge, skills, as well as ethical principles focused on optimum patient care while taking all appropriate measures to relieve suffering. The healthcare team should give primary importance to the expressed desires of the patient tempered by the judgement and legal responsibilities of each licensed health professional as to what is in the patient's best interest.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Informs healthcare professionals about acceptable practices under Federal and state policies.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Food, Drugs and Cosmetics

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

N.C. Gen. Stat. § 106-121

§ 106-121. Definitions and general considerations

For the purpose of this Article:

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(14b) The term "practitioner" means a physician, dentist, veterinarian, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a drug so long as such activity is within the normal course of professional practice or research.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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NORTH DAKOTA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 19. Foods, Drugs, Oils, and Compounds
  Chapter 19-03.1. Uniform Controlled Substances Act

- PAIN TREATMENT ACT (*Part of Uniform Controlled Substances Act*)
  Title 19. Foods, Drugs, Oils, and Compounds; Chapter 19-03.3. Controlled Substances for Care and Treatment

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 43. Occupations and Professions; Chapter 43-17. Physicians and Surgeons

- PHARMACY PRACTICE ACT
  Title 43. Occupations and Professions; Chapter 43-15. Pharmacists

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  No policy found

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 50. State Board of Medical Examiners

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 61. State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HOMICIDE
  Title 12.1. Criminal Code; Chapter 12.1-16. Homicide

- FOOD, DRUGS AND COSMETICS
  Title 19. Foods, Drugs, Oils, and Compounds; Chapter 19-02.1. Food, Drug, and Cosmetics

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Pain Treatment Act		●			●			●
Medical Practice Act[1]								
Pharmacy Practice Act			●					
REGULATIONS								
Controlled Substances[2]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Homicide								●
Food, Drugs and Cosmetics			●					

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Pain Treatment Act[1]								
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances[2]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Homicide[1]								
Food, Drugs and Cosmetics[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

NORTH DAKOTA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.D. Cent. Code, § 19-03.1-01

19-03.1-01. Definitions.

As used in this chapter and in chapters 19-03.2 and 19-03.4, unless the context otherwise requires:

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24. "Practitioner" means:

a. A physician, dentist, veterinarian, pharmacist, scientific investigator, or other person licensed, registered, or otherwise permitted by the jurisdiction in which the individual is practicing to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research.

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(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NORTH DAKOTA

STATUTES

Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.D. Cent. Code, § 19-03.3-01 – § 19-03.3-06

19-03.3-01. Definitions.

As used in this chapter, unless the context otherwise requires:

1. "Board" means the state board of medical examiners.

2. "Pain" means acute pain and chronic pain. Acute pain is the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus and typically is associated with invasive procedures, trauma, or disease, and is generally time-limited. Chronic pain is a state that persists beyond the usual course of an acute disease or healing of an injury or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

3. "Physician" means a physician licensed by the board.

19-03.3-02. Prescription or administration of drugs by physician.

(+) *CRITERION 2:*
Pain management is part of medical practice

Notwithstanding any other provision of law, a physician may prescribe or administer controlled substances to a patient in the course of the physician's treatment of the patient for pain. A physician shall keep records of purchases and disposals of controlled substances prescribed or administered under this section. The records must include the date of purchase, the date of sale or administration by the physician, the name and address of the patient, and the reason for the prescribing or the administering of the substances to the patient.

19-03.3-03. Restriction by hospital or health care facility of prescribed drug use prohibited.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Attempts to provide a secure environment for physicians prescribing in their healthcare facility.

No hospital or health care facility may forbid or restrict the use of controlled substances when prescribed or administered by a physician having staff privileges at that hospital or health care facility for a patient diagnosed and treated by a physician for pain.

19-03.3-04. Disciplinary action for prescribing or administering drug treatment prohibited.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

The board may not discipline a physician for prescribing or administering controlled substances in the course of treatment of a patient for pain under this chapter.

19-03.3-05. Application.

This chapter does not apply to a person being treated by a physician for chemical dependency because of the person's use of controlled substances not related to treatment for pain. This chapter does not authorize a physician to prescribe or administer any drug legally classified as a controlled substance or as an addictive or dangerous drug for other than medically accepted therapeutic purposes. A person to whom controlled substances are prescribed or administered for pain is not exempt from section 39-08-01 or 39-20-04.1.

19-03.3-06. Cancellation, revocation, or suspension of physician's license.

This chapter does not limit the authority of the board to cancel, revoke, or suspend the license of any physician who:

1. Prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed.

2. Fails to keep complete and accurate records of purchases and disposals of controlled substances listed in chapter 19-03.1.

3. Writes false or fictitious prescriptions for controlled substances scheduled in chapter 19-03.1.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3: Opioids are part of professional practice*

N.D. Cent. Code, § 43-15-01

43-15-01. Definitions.

In this chapter, unless the context or subject matter otherwise requires:

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25. "Practitioner" means an individual licensed, registered, or otherwise authorized by the jurisdiction in which the individual is practicing to prescribe drugs in the course of professional practice.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

NORTH DAKOTA

STATUTES

Homicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.D. Cent. Code, § 12.1-16-06

12.1-16-06. Construction.

Sections 12.1-16-04 through 12.1-16-06 do not preclude the use of medications or procedures necessary to relieve a person's pain or discomfort if the use of the medications or procedures is not intentionally or knowingly prescribed or administered to cause the death of that person. In addition, sections 12.1-16-04 through 12.1-16-06 do not preclude the withholding or withdrawal of life-prolonging treatment pursuant to state or federal law.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians that there is an important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment.

STATUTES

Food, Drug and Cosmetic Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

N.D. Cent. Code, § 19-02.1-01

19-02.1-01. Definitions.

For the purpose of this chapter:

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20. "Practitioner" means an individual licensed, registered, or otherwise authorized by the jurisdiction in which the individual is practicing to prescribe drugs in the course of professional practice which are subject to this chapter.

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(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OHIO

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 37. Health, Safety, Morals; Chapter 3719. Controlled Substances

- MEDICAL PRACTICE ACT
  Title 47. Occupations, Professions; Chapter 4731. Physicians, Limited Practitioners

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Title 47. Occupations, Professions; Chapter 4731. Physicians, Limited Practitioners; §4731.052

- PHARMACY PRACTICE ACT
  Title 47. Occupations, Professions; Chapter 4729. Pharmacists, Dangerous Drugs

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  4729. State Board of Pharmacy; 4729-9. Dangerous Drugs

- MEDICAL BOARD REGULATIONS
  4731. State Medical Board

- PHARMACY BOARD REGULATIONS
  4729. State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- ASSISTED SUICIDE
  Title 21. Courts – Probate – Juvenile; Chapter 2133. Modified Uniform Rights of the Terminally Ill Act and the DNR Identification and Do-Not-Resuscitate Order Law

- ASSISTED SUICIDE
  Title 37. Health, Safety, Morals; Chapter 3795. Assisted Suicide

- HOSPICE CARE
  3701. Department of Health, Administration and Director; Chapter 3701-19. Hospice Care Programs

OH

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act								●
Intractable Pain Treatment Act					●	●		●
Pharmacy Practice Act			●					
REGULATIONS								
Controlled Substances[1]								
Medical Board					●	●	●	●
Pharmacy Board			●					
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Assisted Suicide								●
Assisted Suicide								●
Hospice Care								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Intractable Pain Treatment Act				●				●
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances[1]								
Medical Board				●				●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Assisted Suicide[1]								
Assisted Suicide[1]								
Hospice Care[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

OHIO

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

ORC Ann. 3719.06

§ 3719.06. Authority of licensed health professional; contents of prescription

(A) (1) A licensed health professional authorized to prescribe drugs, if acting in the course of professional practice, in accordance with the laws regulating the professional's practice, and in accordance with rules adopted by the state board of pharmacy, may, except as provided in division (A)(2) of this section, do the following:

(a) Prescribe schedule II, III, IV, and V controlled substances;

(b) Administer or personally furnish to patients schedule II, III, IV, and V controlled substances;

(c) Cause schedule II, III, IV, and V controlled substances to be administered under the prescriber's direction and supervision.

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(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

ORC Ann. 4731.283

§ 4731.283. Continuing education concerning intractable pain

Not later than ninety days after the effective date of this section, the state medical board shall approve one or more continuing medical education courses of study included within the programs certified by the Ohio state medical association and the Ohio osteopathic association pursuant to *section 4731.281 [4731.28.1] of the Revised Code* that assist doctors of medicine and doctors of osteopathic medicine in diagnosing and treating intractable pain, as defined in *section 4731.052 [4731.05.2] of the Revised Code*.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (continuing education) to provide practitioners information/education about pain management

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

ORC Ann. 4731.052

[§ 4731.05.2] § 4731.052 Management of intractable pain with dangerous drugs.

(A) As used in this section:

(1) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(2) "Intractable pain" means a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found.

(3) "Physician" means an individual authorized under this chapter to practice medicine and surgery or osteopathic medicine and surgery.

(B) The state medical board shall adopt rules in accordance with Chapter 119. of the Revised Code that establish standards and procedures to be followed by physicians in the diagnosis and treatment of intractable pain, including standards for managing intractable pain by prescribing, personally furnishing, or administering dangerous drugs in amounts or combinations that may not be appropriate when treating other medical conditions. In developing the rules, the board shall consult with and permit review by physicians who are experienced in the diagnosis and treatment of intractable pain.

(C) When a physician diagnoses an individual as having intractable pain, the physician may treat the pain by managing it with dangerous drugs in amounts or combinations that may not be appropriate when treating other medical conditions. The physician's diagnosis shall be made after having the individual evaluated by one or more other physicians who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain. The physician's diagnosis and treatment decisions shall be made according to accepted and prevailing standards for medical care. The physician shall maintain a record of all of the following:

(1) Medical history and physical examination of the individual;

(2) The diagnosis of intractable pain, including signs, symptoms, and causes;

(3) The plan of treatment proposed, the patient's response to treatment, and any modification to the plan of treatment;

(4) The dates on which dangerous drugs were prescribed, furnished, or administered, the name and address of the individual to or for whom the dangerous drugs were prescribed, dispensed, or administered, and the amounts and dosage forms for the dangerous drugs prescribed, furnished, or administered;

(5) A copy of the report made by the physician or the physician to whom referral for evaluation was made under this division.

(D) A physician who treats intractable pain by managing it with dangerous drugs is not subject to disciplinary action by the board under section 4731.22 of the Revised Code solely because the physician treated the intractable pain with dangerous drugs. The physician is subject to disciplinary action only if the dangerous drugs are not prescribed, furnished, or administered in accordance with this section and the rules adopted under it.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (rules) for the Board to ensure that pain management is an essential part of patient care.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY B:
Mandated consultation

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

ORC Ann. 4729.01

§ 4729.01. Definitions

As used in this chapter:

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(I) "Licensed health professional authorized to prescribe drugs" or "prescriber" means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including only the following:

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

OAC Ann. 4731-21-01 – 4731-21-06

4731-21-01 Definitions.

As used in Chapter 4731-21 of the Administrative Code:

(A) "Addiction" means a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological and/or physical consequences, the continued use of which results in a decreased quality of life. Physical dependence alone is not evidence of addiction.

(B) "Believes" or "has reason to believe" does not require absolute certainty or complete unquestioning acceptance; but only an opinion based on reasonable information that a patient is suffering from addiction or drug abuse or engaging in diversion of drugs.

(C) "Board" means the state medical board of Ohio.

(D) "Diversion" means the conveyance of a prescription drug to a person other than the person for whom the drug was prescribed or dispensed by a practitioner.

(E) "Drug abuse" means a maladaptive or inappropriate use or overuse of a medication.

(F) "Emergency" means an unforeseen combination of circumstances or the resulting state that calls for immediate action.

(G) "Intractable pain" means a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found. "Intractable pain" does not include pain experienced by a patient with a terminal condition. "Intractable pain" does not include the treatment of pain associated with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

(H) "Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

(I) "Physical dependence" means a physiologic state of adaptation to a specific drug or medication characterized by the development of a withdrawal syndrome following abrupt cessation of a drug or on administration of an antagonist.

(J) "Practitioner" means an individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatry and practicing within his or her scope of practice as defined by *section 4731.51 of the Revised Code*.

(K) "Prescription drug" means a drug which under state or federal law may be administered or dispensed only by or upon the order of a practitioner and includes the term "dangerous drug" as defined by *section 4729.02 of the Revised Code*.

(L) "Podiatrist" means an individual holding a certificate under chapter 4731. of the Revised Code to practice podiatry and practicing within his or her scope of practice as defined by *section 4731.51 of the Revised Code*.

(M) "Protracted basis" mea ns for a period in excess of twelve continuous weeks.

(N) "Terminal condition" means an irreversible, incurable, and untreatable condition caused by disease, illness, or injury from which, to a reasonable degree of medical certainty as determined in accordance with reasonable medical standards by a patient's attending medical doctor or doctor of osteopathic medicine and one other individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery who has examined the patient, both of the following apply:

(1) There can be no recovery;

(2) Death is likely to occur within a relatively short time if life-sustaining treatment is not administered.

[CONTINUED ON NEXT PAGE]

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

(O) "Tolerance" means decreasing response to the same dosage of a prescription drug over time as a result of physiologic adaptation to that drug.

(P) "Utilizing prescription drugs" means prescribing, administering, dispensing, supplying, selling or giving a prescription drug.

4731-21-02 Utilizing prescription drugs for the treatment of intractable pain.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(A) When utilizing any prescription drug for the treatment of intractable pain on a protracted basis or when managing intractable pain with prescription drugs in amounts or combinations that may not be appropriate when treating other medical conditions, a practitioner shall comply with accepted and prevailing standards of care which shall include, but not be limited to, the following:

(1) An initial evaluation of the patient shall be conducted and documented in the patient's record that includes a relevant history, including complete medical, pain, alcohol and substance abuse histories; an assessment of the impact of pain on the patient's physical and psychological functions; a review of previous diagnostic studies and previously utilized therapies; an assessment of coexisting illnesses, diseases or conditions; and an appropriate physical examination;

(2) A medical diagnosis shall be established and documented in the patient's medical record that indicates not only the presence of intractable pain but also the signs, symptoms, and causes and, if determinable, the nature of the underlying disease and pain mechanism;

(3) An individualized treatment plan shall be formulated and documented in the patient's medical record. The treatment plan shall specify the medical justification of the treatment of intractable pain by utilizing prescription drugs on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, the intended role of prescription drug therapy within the overall plan, and, when applicable, documentation that other medically reasonable treatments for relief of the patient's intractable pain have been offered or attempted without adequate or reasonable success. The prescription drug therapy shall be tailored to the individual medical needs of each patient. The practitioner shall document the patient's response to treatment and, as necessary, modify the treatment plan;

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY B:
Mandated consultation

(4)(a) The practitioner's diagnosis of intractable pain shall be made after having the patient evaluated by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain. For purposes of this rule, a practitioner "specializes" if the practitioner limits the whole or part of his or her practice, and is qualified by advanced training or experience to so limit his or her practice, to the particular anatomic area, system, or organ of the body perceived as the source of the pain. The evaluation shall include review of all available medical records of prior treatment of the intractable pain or the condition underlying the intractable pain; a thorough history and physical examination; and testing as required by accepted and prevailing standards of care. The practitioner shall maintain a copy of any report made by any practitioner to whom referral for evaluation was made under this paragraph. A practitioner shall not provide an evaluation under this paragraph if that practitioner would be prohibited by *sections 4731.65* to *4731.69 of the Revised Code* or any other rule adopted by the board from providing a designated health service upon referral by the treating practitioner; and

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Practitioners are not required to obtain a consultation when a patient has been evaluated previously. However, the policy continues to mandate consultation for all other patients with intractable pain.

(b) The practitioner shall not be required to obtain such an evaluation, if the practitioner obtains a copy of medical records or a detailed written summary thereof showing that the patient has been evaluated and treated within a reasonable period of time by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain and the treating practitioner is satisfied that he or she can rely on that evaluation for purposes of meeting the further requirements of this chapter of the Administrative Code. The practitioner shall obtain and review all available medical records or detailed written summaries thereof of prior treatment of the intractable pain or the condition underlying the intractable pain. The practitioner shall maintain a copy of any record or report of any practitioner on which the practitioner relied for purposes of meeting the requirements under this paragraph; and

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

(5) The practitioner shall ensure and document in the patient's record that the patient or other individual who has the authority to provide consent to treatment on behalf of that patient gives consent to treatment after being informed of the benefits and risks of receiving prescription drug therapy on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, and after being informed of available treatment alternatives.

(B) Upon completion and satisfaction of the conditions prescribed in paragraph (A) of this rule, and upon a practitioner's judgment that the continued utilization of prescription drugs is medically warranted for the treatment of intractable pain, a practitioner may utilize prescription drugs on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, provided that the practitioner continues to adhere to accepted and prevailing standards of care which shall include, but not be limited to, the following:

(1) Patients shall be seen by the practitioner at appropriate periodic intervals to assess the efficacy of treatment, assure that prescription drug therapy remains indicated, evaluate the patient's progress toward treatment objectives and note any adverse drug effects. During each visit, attention shall be given to changes in the patient's ability to function or to the patient's quality of life as a result of prescription drug usage, as well as indications of possible addiction, drug abuse or diversion. Compliance with this paragraph of the rule shall be documented in the patient's medical record;

(2) Some patients with intractable pain may be at risk of developing increasing prescription drug consumption without improvement in functional status. Subjective reports by the patient should be supported by objective data. Objective measures in the patient's condition are determined by an ongoing assessment of the patient's functional status, including the ability to engage in work or other gainful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient. Compliance with this paragraph of the rule shall be documented in the patient's medical record;

(3) Based on evidence or behavioral indications of addiction or drug abuse, the practitioner may obtain a drug screen on the patient. It is within the practitioner's discretion to decide the nature of the screen and which type of drug(s) to be screened. If the practitioner obtains a drug screen for the reasons described in this paragraph, the practitioner shall document the results of the drug screen in the patient's medical record. If the patient refuses to consent to a drug screen ordered by the practitioner, the practitioner shall make a referral as provided in paragraph (C) of this rule;

(4) The practitioner shall document in the patient's medical record the medical necessity for utilizing more than one controlled substance in the management of a patient's intractable pain; and

(5) The practitioner shall document in the patient's medical record the name and address of the patient to or for whom the prescription drugs were prescribed, dispensed, or administered, the dates on which prescription drugs were prescribed, dispensed, or administered, and the amounts and dosage forms of the prescription drugs prescribed, dispensed, or administered, including refills.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

(C) If the practitioner believes or has reason to believe that the patient is suffering from addiction or drug abuse, the practitioner shall immediately consult with an addiction medicine or other substance abuse specialist. For purposes of this rule, "addiction medicine or substance abuse specialist" means a physician who is qualified by advanced formal training in addiction medicine or other substance abuse specialty, and includes a medical doctor or doctor of osteopathic medicine who is certified by a specialty examining board to so limit the whole or part of his or her practice. Prescription drug therapy may be continued consistent with the recommendations of the consultation, including, if the consulting addiction medicine or other substance abuse specialist recommends that it is necessary, prompt referral to an addiction medicine or other substance abuse specialist for physical examination and evaluation of the patient and a review of the referring practitioner's medical records of the patient. The practitioner shall document the recommendations of the consultation in the patient's record. The practitioner shall continue to actively monitor the patient for signs and symptoms of addiction, drug abuse or diversion. The practitioner shall maintain a copy of any written report made by any practitioner to whom referral for evaluation was made under this paragraph.

4731-21-03 Continuing Medical Education.

The board encourages those practitioners who encounter patients with intractable pain in the usual course of their practices to complete continuing medical education related to the treatment of intractable pain, including coursework related to pharmacology, alternative methods of pain management and treatment, and addiction medicine.

4731-21-04 Tolerance, Physical Dependence and Addiction.

(A) Physical dependence and tolerance by themselves do not indicate addiction.

(B) Physical dependence and tolerance are normal physiological consequences of extended opioid therapy, and do not, in the absence of other indicators of drug abuse or addiction, require reduction or cessation of opioid therapy.

4731-21-05 Violations.

A violation of any provision of any rule in this chapter of the Administrative Code, as determined by the board, shall constitute "failure to use reasonable care discrimination in the administration of drugs," as that clause is used in division (B)(2) of *section 4731.22 of the Revised Code*; "selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of *section 4731.22 of the Revised Code*, if done knowingly or recklessly, as those words are defined in *section 2901.22 of the Revised Code*; and "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of *section 4731.22 of the Revised Code*.

4731-21-06 Exceptions.

(A) A practitioner who treats pain by utilizing prescription drugs is not subject to disciplinary action pursuant to this chapter of the Administrative Code under the following circumstances:

(1) The treatment of pain for a patient with a terminal condition:

(2) The treatment of pain associated with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition;

(3) Treatment utilizing only drugs that do not exert their effects at the central nervous system level; and

(4) Treatment utilizing only drugs that are not controlled substances and are classified as antidepressants.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (encouraging continuing education) to provide practitioners information/education about pain management.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Exempts practitioners who treat pain in patients who do not meet the definition of "intractable pain" from these statutory requirements.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

[CONTINUED]

(B) A practitioner who treats intractable pain by utilizing prescription drugs is not subject to disciplinary action by the board under *section 4731.22 of the Revised Code* solely because the practitioner treated the intractable pain with prescription drugs. The practitioner is subject to disciplinary action only if the prescription drugs are not utilized in accordance with *section 4731.052 of the Revised Code* and the rules adopted under this chapter of the Administrative Code.

(C) A Medical doctor or doctor of osteopathic medicine who provides comfort care as described in division (E)(1) of *section 2133.12 of the Revised Code* to a patient with a terminal condition is not subject to disciplinary action by the board under *section 4731.22 of the Revised Code* if the treatment of pain for a patient with a terminal condition is provided pursuant to the requirements of *section 2133.11 of the Revised Code*.

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

OAC Ann. 4729-5-01

4729-5-01 Definitions.

As used in Chapter 4729. of the Revised Code:

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(M) "Prescriber" means any person authorized by the Revised Code to prescribe dangerous drugs as part of their professional practice.

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(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Assisted Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

ORC Ann. 2133.11

§ 2133.11. Immunity from civil or criminal liability or professional disciplinary action

(A) Subject to division (D) of this section, an attending physician, consulting physician, health care facility, and health care personnel acting under the direction of an attending physician are not subject to criminal prosecution, are not liable in damages in a tort or other civil action, and are not subject to professional disciplinary action for any of the following:

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(6) Prescribing, dispensing, administering, or causing to be administered any particular medical procedure, treatment, intervention, or other measure to a qualified patient or other patient, including, but not limited to, prescribing, personally furnishing, administering, or causing to be administered by judicious titration or in another manner any form of medication, for the purpose of diminishing the qualified patient's or other patient's pain or discomfort and not for the purpose of postponing or causing the qualified patient's or other patient's death, even though the medical procedure, treatment, intervention, or other measure may appear to hasten or increase the risk of the patient's death, if the attending physician so prescribing, dispensing, administering, or causing to be administered or the health care personnel acting under the direction of the attending physician so dispensing, administering, or causing to be administered are carrying out in good faith the responsibility to provide comfort care described in division (E)(1) of *section 2133.12 of the Revised Code*.

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STATUTES

Assisted Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

ORC Ann. 3795.03

§ 3795.03 Exceptions to provisions

Nothing in section 3795.01 or 3795.02 of the Revised Code shall do any of the following:

(A) Prohibit or preclude a physician, certified nurse practitioner, certified nurse-midwife, or clinical nurse specialist who carries out the responsibility to provide comfort care to a patient in good faith and while acting within the scope of the physician's or nurse's authority from prescribing, dispensing, administering, or causing to be administered any particular medical procedure, treatment, intervention, or other measure to the patient, including, but not limited to, prescribing, personally furnishing, administering, or causing to be administered by judicious titration or in another manner any form of medication, for the purpose of diminishing the patients' pain or discomfort and not for the purpose of postponing or causing the patient's death, even though the medical procedure, treatment, intervention, or other measure may appear to hasten or increase the risk of the patient's death;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospice Care

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes mechanisms for hospices to ensure that pain management is an essential part of patient care.

OAC Ann. 3701-19-10

3701-19-10 Medical director.

The medical director of a hospice care program shall have overall responsibility for the medical component of the program.

Interpretive guideline: The medical director may be either a physician who is a paid or contractual staff member or volunteer whose duties shall include:

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(C) Consulting with attending physicians, as requested, regarding pain and symptom management;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OKLAHOMA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 63. Public Health and Safety; Chapter 2. Uniform Controlled Dangerous Substances Act

- MEDICAL PRACTICE ACT
  Title 59. Professions and Occupations; Chapter 11. Medicine

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Title 59. Professions and Occupations; Chapter 14. Osteopathic Medicine Act

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 59. Professions and Occupations; Chapter 8. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 475. Oklahoma State Bureau of Narcotics and Dangerous Drugs Control

- MEDICAL BOARD REGULATIONS
  Title 435. State Board of Medical Licensure and Supervision

- OSTEOPATHIC BOARD REGULATIONS
  Title 510. State Board of Osteopathic Examiners

- PHARMACY BOARD REGULATIONS
  Title 535. Oklahoma State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  Oklahoma State Board of Medical Licensure and Supervision. *Use of Controlled Substances for the Treatment of Pain*. Adopted: March 10, 2005.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- NURSING HOME CARE ACT
  Title 63. Public Health and Safety; Chapter 1. Public Health Code; Article 19. Nursing Home Care Act

- ASSISTED SUICIDE PREVENTION ACT
  Title 63. Public Health and Safety; Chapter 61B. Assisted Suicide Prevention Act

- HOSPITAL STANDARDS
  Title 310. Oklahoma State Department of Health; Chapter 667. Hospital Standards; Subchapter 3. Patient Rights

- NURSING AND SPECIALIZED FACILITIES
  Title 310. Oklahoma State Department of Health; Chapter 675. Nursing and Specialized Facilities;
  Subchapter 7. Administration
  Subchapter 9. Resident Care Services
  Subchapter 13. Staff Requirements

OK

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act	●	●	●	●	●			●
Medical Practice Act		●						
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					
Medical Board		●						●
Osteopathic Board		●	●			●		●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Nursing Home Care Act								●
Assisted Suicide Prevention Act								●
Hospital Standards								●
Nursing and Specialized Facilities								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

OK

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act			●					
Medical Practice Act								●
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board				●				●
Osteopathic Board				●				●
Pharmacy Board								●
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Nursing Home Care Act[1]								
Assisted Suicide Prevention Act[1]								
Hospital Standards[1]								
Nursing and Specialized Facilities[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
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OKLAHOMA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

63 Okl. St. § 2-101

§ 2-101. Definitions

As used in the Uniform Controlled Dangerous Substances Act, Section 2-101 et seq. of this title:

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15. "Drug-dependent person" means a person who is using a controlled dangerous substance and who is in a state of psychic or physical dependence, or both, arising from administration of that controlled dangerous substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects, or to avoid the discomfort of its absence;

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63 Okl. St. § 2-551

§ 2-551. Appropriate pain management--high dosages of controlled dangerous drugs

A. Schedule II, III, IV and V controlled dangerous drugs have useful and legitimate medical and scientific purposes and are necessary to maintain the health and general welfare of the people of this state.

B. The State of Oklahoma recognizes that principles of quality medical practice dictate that the people of the State of Oklahoma have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as to reduce the morbidity, and costs associated with untreated or inappropriately treated pain. The State of Oklahoma encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic. It is especially important for patients who experience pain as a result of terminal illness.

C. If, in the judgment of the medical doctor or the doctor of osteopathic medicine, appropriate pain management warrants a high dosage of controlled dangerous drugs and the benefit of the relief expected outweighs the risk of the high dosage, the medical doctor or doctor of osteopathic medicine may administer such a dosage, even if its use may increase the risk of death, so long as it is not also furnished for the purpose of causing, or the purpose of assisting in causing, death for any reason and so long as it falls within policies, guidelines and rules of the Oklahoma State Board of Medical Licensure and Supervision or the Oklahoma State Board of Osteopathic Examiners.

D. The Oklahoma State Board of Medical Licensure and Supervision and the Oklahoma State Board of Osteopathic Examiners shall issue policies, guidelines or rules that ensure that physicians who are engaged in the appropriate treatment of pain are not subject to disciplinary action, and the Boards shall consider policies and guidelines developed by national organizations with expertise in pain medicine or in a medical discipline for this purpose.

(+) *CRITERION 1:*
Controlled substances are necessary for public health

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (issuing policies) for the Board to ensure that pain management is an essential part of patient care.

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OKLAHOMA

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

59 Okl. St. § 492

§ 492. Designation of physicians—Employment by hospitals—Practice of medicine defined—Services rendered by trained assistants—Persons practicing nonallopathic healing

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C. The definition of the practice of medicine and surgery shall include, but is not limited to:

1. Advertising, holding out to the public, or representing in any manner that one is authorized to practice medicine and surgery in this state;

2. Any offer or attempt to prescribe, order, give, or administer any drug or medicine and surgery for the use of any other person, except as otherwise authorized by law;

3. a. Any offer or attempt, except as otherwise authorized by law, to prevent, diagnose, correct, or treat in any manner or by any means, methods, devises, or instrumentalities except for manual manipulation any disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of any person, including the management of pregnancy and parturition, except as otherwise authorized by law.

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(+) *CRITERION 2:*
Pain management is part of medical practice

59 Okl. St. § 509

509. Unprofessional Conduct - Definition

"The words 'Unprofessional Conduct' as used in Sections 481 through 514 of this title are hereby declared to include, but shall not be limited to, the following:

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16. Prescribing, dispensing or administering of controlled substances or narcotic drugs in excess of the amount considered good medical practice, or prescribing, dispensing or administering controlled substances or narcotic drugs without medical need in accordance with published standards;

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: "Excess" implies there is a limit, but the limit is not specified.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OKLAHOMA

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

O.A.C. § 475:30-1-3.

475:30-1-3. Purpose of issuance of prescriptions

(a) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by a registered or otherwise authorized individual practitioner acting in the usual course of his/her professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription, as the filling of a prescription is not incumbent on the pharmacy. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Title 63 Okl.St.Ann. § § 2-309 and 2-312, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled dangerous substances.

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REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

OAC 435:10-7-4

435:10-7-4 Unprofessional Conduct

"The Board has the authority to revoke or take other disciplinary action against a licensee or certificate holder for unprofessional conduct. Pursuant to 59 O.S., 1991, Section 509, "Unprofessional Conduct" shall be considered to include :

(1) Indiscriminate or excessive prescribing, dispensing, or administering of Controlled or Narcotic Drugs.

(2) Prescribing, dispensing or administering of Controlled substances or Narcotic drugs in excess of the amount considered good medical practice or prescribing, dispensing or administering controlled substances or narcotic drugs without medical need in accordance with published standard.

. . .

(25) Except as otherwise permitted by law, prescribing, selling, administering, distributing, ordering, or giving to a habitue or addict or any person previously drug dependent, any drug legally classified as a controlled substance or recognized as an addictive or dangerous drug.

. . .

(47) Causing, or assisting in causing, the suicide, euthanasia or mercy killing of any individual; provided that it is not causing, or assisting in causing, the suicide, euthanasia or mercy killing of any individual to prescribe, dispense or administer medical treatment for the purpose of alleviating pain or discomfort in accordance with Oklahoma Administrative Code 435:10-7-11, even if such use may increase the risk of death, so long as it is not also furnished for the purpose of causing, or the purpose of assisting in causing, death for any reason.

. . .

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: "Excess" implies there is a limit, but the limit is not specified.

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

COMMENT: Oklahoma law does not seem to create an exemption for patients with pain and a history of addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OKLAHOMA

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

O.A.C. § 435:10-7-11

435:10-7-11 Use of controlled substances for the management of chronic pain

The Board has recognized that principles of quality medical practice dictate that the people of the State of Oklahoma have access to appropriate and effective pain relief and has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:(1) A medical history and physical examination must be obtained, evaluated and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

(2) The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(3) The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including:

(A) urine/serum medication levels screening when requested;

(B) number and frequency of all prescription refills; and

(C) reasons for which drug therapy may be discontinued (e.g. violation of agreement)

(4) The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

(5) The physician should be willing to refer the patient, as necessary, for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

(6) Records should remain current and be maintained in an accessible manner, readily available for review. The physician should keep accurate and complete records to include:

(A) the medical history and physical examination (including vital signs),

(B) diagnostic, therapeutic and laboratory results,

(C) evaluations, consultations and follow-up evaluations,

(D) treatment objectives,

(E) discussion of risks and benefits,

(F) informed consent,

(G) treatments,

(H) medications (including date, type, dosage and quantity prescribed),

(I) instructions and agreements and

(J) periodic reviews.

(7) To prescribe, dispense or administer controlled substances, the physician must be licensed in Oklahoma and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing controlled substances as well as applicable state regulations.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OKLAHOMA

REGULATIONS

Osteopathic Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: "Excessive" implies there is a limit, but the limit is not specified.

O.A.C. § 510:5-7-1.

510:5-7-1. Unprofessional conduct relating to prescribing or dispensing dangerous drugs

The Board has the right to refuse to issue, renew or reinstate a license and may revoke a license or impose other appropriate sanctions for unprofessional conduct. In addition to those acts of unprofessional conduct listed in Title 59 O.S., Section 637 the following acts shall be included without limiting, in any way the Board's ability to interpret other acts as unprofessional conduct:
(1) Indiscriminate or excessive prescribing, dispensing or administering controlled dangerous drugs.
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O.A.C. § 510:5-9-2.

510:5-9-2. Guidelines and requirements

This rule requires that diagnosis be documented, it requires that certain records be maintained, and it requires that the physician must discuss the risks and benefits with the patient or the patient's guardian.(1) To treat a patient's intractable pain, as long as the benefit of the expected relief outweighs the risk, even if the use of the drug increases the risk of death, so long as it is not furnished for the purpose of causing, or the purpose of assisting in causing death, the physician may prescribe or administer Schedule II, III, IV or V controlled dangerous substances or other pain relieving drugs in higher than normal dosages when, in that physician's judgment, the higher dosages are necessary to produce the desired therapeutic effect.

(2) The determination of intractable pain must include a complete medical history and physical examination which includes an assessment of the patient's pain, physical and psychological function, substance abuse history, underlying or co-existing diseases or conditions and the presence of a recognized medical indication for the use of an analgesic.

(3) The treatment plan must state objectives by which treatment success can be evaluated, such as pain relief and or improved physical and psychological function, and must indicate what further diagnostic evaluations or other treatments are planned. The drug therapy must be tailored to the individual needs of each patient.

(4) The course of treatment and any new information about the etiology of the intractable pain must be reviewed periodically, at least annually, with consideration given to referral for a current second opinion. The continuation or modification of treatment will depend on the results of this review and the evaluation of the patient's progress toward the treatment objectives. If the patient has not improved, the physician must assess the appropriateness of continuing the current therapy and the trial of other modalities.

(5) The management of intractable pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists, and may include the use of agreements between the physician and patient specifying rules for medication use and consequences for its misuse.

(6) The physician must discuss the risks and benefits of the use of controlled substances with the patient or the patient's guardian and obtain informed consent prior to proceeding if it substantially increases the risk of death.

(7) Accurate and complete records documenting these requirements must be kept.

(8) To prescribe controlled substances, the physician must be licensed in Oklahoma, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions.

(9) Expert clinical testimony may be used to prove a violation of this rule. As used herein, a "clinical expert" is a physician who, by reason of specialized education or substantial relevant experience in pain management, has knowledge regarding current standards, practices and guidelines.

(10) Nothing in this rule shall limit a physician's authority to prescribe or administer prescription drug products beyond the customary indications as noted in the manufacturer's package insert for use in treating intractable pain, provided the drug is recognized for treatment of intractable pain in standard reference compendia or medical literature.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY B:
Mandated consultation

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that it is appropriate medical practice for physicians to prescribe for indications not listed in product package inserts, and is consistent with federal law.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

O.A.C. § 535:10-3-1.2.

535:10-3-1.2. Violations of professional conduct

Violations of the rules of professional conduct, which may also be called unprofessional conduct, include, but are not limited to, the following:

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(10) Not attempting to address the possible addiction or dependency of a patient to a drug dispensed by the pharmacist, if there is reason to believe that the patient may be dependent or addicted.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY C:
Conflicting or inconsistent policies or provisions

COMMENT:
Implementing this policy could be complicated by Oklahoma's definition of dependence (addiction) in statute, which confuse physical dependence with addiction, and can lead to patients with pain being misidentified as "addicts."

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OKLAHOMA

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Number 138

SUBJECT: Use of Controlled Substances for the Treatment of Pain

POLICY:

The Oklahoma State Board of Medical Licensure and Supervision (Board) recognizes that principles of quality medical practice dictate that the people of the State of Oklahoma have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as to reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Board is obligated under the laws of the State of Oklahoma to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state and/or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OKLAHOMA

STATUTES

Nursing Home Care Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (promulgating rules) for nursing homes to ensure that pain management is an essential part of patient care.

63 Okl. St. § 1-1918B

§ 1-1918B. Intent of Legislature regarding nursing home residents' pain--Nursing homes to assess residents' pain--Rules and regulations regarding pain management

A. It is the intent of the Legislature that pain experienced by nursing home residents be assessed and treated promptly, effectively, and for as long as pain persists.

B. On and after July 1, 2005, every nursing facility licensed pursuant to the Nursing Home Care Act shall, as a condition of licensure, include pain as an item to be assessed at the same time as vital signs are taken. The nursing facility shall ensure that pain assessment is performed in a consistent manner that is appropriate to the patient. The pain assessment shall be noted in the patient's chart in a manner consistent with other vital signs.

C. The State Board of Health shall promulgate rules, pursuant to recommendations issued by the State Advisory Council on Pain Management, for assessing and documenting pain.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that pain management is an essential part of nursing home care.

STATUTES

Assisted Suicide Prevention Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

63 Okl. St. § 3141.4

§ 3141.4. Acts not constituting violations

A. A licensed health care professional who administers, prescribes, or dispenses medications or procedures for the purpose of alleviating pain or discomfort, even if their use may increase the risk of death, shall not be deemed to have violated Section 3 of this act or Section 813 or 814 of Title 21 of the Oklahoma Statutes so long as such medications or procedures are not also furnished for the purpose of causing, or the purpose of assisting in causing, death for any reason.

B. A licensed health care professional who withholds or withdraws a medically administered, life-sustaining procedure does not violate Section 3 of this act or Sections 813 or 814 of Title 21 of the Oklahoma Statutes.

C. This section shall not be construed to affect the duty of care or the legal requirements concerning acts or omissions under subsections A or B of this section.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OKLAHOMA

REGULATIONS

Hospital Standards

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (policies and procedures) for hospitals to ensure that pain management is an essential part of patient care.

O.A.C. § 310:667-3-3

310:667-3-3 Medical therapies

The policies and procedures concerning medical therapies shall include:

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(4) Policies for patients who are diagnosed as terminal and the therapies which are aimed at optimizing comfort and alleviating pain.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Nursing and Specialized Facilities

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

OKLAHOMA

O.A.C. § 310:675-7-9.1

310:675-7-9.1 Written administrative policies and procedures

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(k) The facility shall adopt a nursing policy and procedure manual, which shall detail all nursing procedures performed within the facility. All procedures shall be in accordance with accepted nursing practice standards, and shall include, but not be limited to, the following:

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(13) Pain assessment and treatment.

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O.A.C. § 310:675-9-1.1et seq

310:675-9-1.1 Nursing and personal care services

(a) The facility shall ensure that resident rights are respected in the provision of care.

(b) Basic nursing and personal care shall be provided for residents as needed.

(1) Nursing care shall include, but not be limited to:

(A) Encouraging residents to be active and out of bed for reasonable time periods.

(B) Measuring resident temperature, blood pressure, pulse and respirations at least once every thirty days and more frequently if warranted by the resident's condition, with the results recorded in the clinical record.

(i) Measuring resident weight at least once every thirty days and more frequently if warranted by the resident's condition, with the results recorded in the clinical record.

(ii) Measuring resident pain whenever vital signs are taken and more frequently if warranted by the resident's condition, with the results recorded in the clinical record.

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310:675-9-5.1 Assessment and care plans

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(c) Efforts shall be made to include the resident and resident's representative in development and implementation of the care planning process.

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(2) Resident pain assessment

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O.A.C. § 310:675-13-5

310:675-13-5 Nursing service

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(i) Inservice. The facility shall provide all direct care staff with two hours of inservice training specific to their job assignment per month. This training shall include, at least, the following:

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(8) Each registered nurse shall be provided training in pain assessment and pain management at the time of orientation and at least once every six months thereafter.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (policies and procedures) for nursing and specialized facilities to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for nursing and specialized facilities to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (care plan) for nursing and specialized facilities to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (inservice training) for nursing and specialized facilities to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OR

OREGON

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 37. Alcoholic Liquors, Controlled Substances, Drugs. Chapter 475. Controlled Substances, Illegal Drug Cleanup, Paraphernalia, Precursors. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Title 52. Occupations and Professions. Chapter 677. Regulation of Medicine, Podiatry and Acupuncture; Physicians and Surgeons; Podiatric Physicians and Surgeons Licensing

- PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Title 52. Occupations and Professions. Chapter 677. Regulation of Medicine, Podiatry and Acupuncture; Physicians and Surgeons; Podiatric Physicians and Surgeons; Administration of Controlled Substances for Intractable Pain

- PHARMACY PRACTICE ACT
  Title 52. Occupations and Professions. Chapter 689. Pharmacists, Drug Outlets, Drug Sales

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Chapter 855. Board of Pharmacy; Division 80. Schedule of Controlled Substances

- MEDICAL BOARD REGULATIONS
  Chapter 847. Board of Medical Examiners

- PHARMACY BOARD REGULATIONS
  Chapter 855. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  Oregon Board of Medical Examiners. *Intractable Pain and Pain Management: BME Statement of Philosophy on Pain Management*. Adopted: ND.

- PHARMACY BOARD POLICY STATEMENT
  Oregon Board of Pharmacy. *Treatment and Management of Pain*. Adopted: June, 2006.

- JOINT BOARD POLICY STATEMENT
  Oregon Pain Management Commission. *Joint Statement on Pain Management*. Adopted: September 15, 2006.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- PAIN MANAGEMENT COMMISSION
  Title 34. Human Services, Juvenile Code, Corrections; Chapter 409. Department of Human Services; Pain Management Commission

- PROFESSIONAL PRACTICE
  Title 52. Occupations and Professions.
  Chapter 670. Occupations and Professions Generally
  Chapter 676. Health Professions Generally

- HOSPITAL LICENSING PROCEDURES
  Chapter 333. Department of Human Services, Public Health; Division 500. Licensing Procedures and Definitions

- PAIN MANAGEMENT COMMISSION
  Chapter 407. Department of Human Services, Administrative Services Division and Director's Office. Division 20. Pain Management Commission

- PERSONAL CARE SERVICES
  Chapter 411. Department of Human Services, Seniors and People with Disabilities Division. Division 34. Personal Care Services

OR

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act		●						●
Pain Treatment Act		●	●		●			
Pharmacy Practice Act			●					●
REGULATIONS								
Controlled Substances[1]								
Medical Board								●
Pharmacy Board			●					●
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement		●		●				●
Pharmacy Board Policy Statement		●	●	●	●			●
Joint Board Policy Statement				●	●			●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Pain Management Commission								●
Professional Practice				●				●
Hospital Licensing Procedures								●
Pain Management Commission								●
Personal Care Services								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Pain Treatment Act[1]								
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement[1]								
Pharmacy Board Policy Statement[1]								
Joint Board Policy Statement[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Pain Management Commission[1]								
Professional Practice[1]								
Hospital Licensing Procedures[1]								
Pain Management Commission[1]								
Personal Care Services[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

ORS § 475.005

475.005. Definitions for ORS 475.005 to 475.285 and 475.940 to 475.999.

As used in *ORS 475.005* to *475.285* and *475.940* to *475.999*, unless the context requires otherwise:

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(18) "Practitioner" means physician, dentist, veterinarian, scientific investigator, certified nurse practitioner, physician assistant or other person licensed, registered or otherwise permitted by law to dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state but does not include a pharmacist or a pharmacy.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

ORS § 677.085

677.085. What constitutes practice of medicine.

A person is practicing medicine if the person does one or more of the following:

(1) Advertise, hold out to the public or represent in any manner that the person is authorized to practice medicine in this state.

(2) For compensation directly or indirectly received or to be received, offer or undertake to prescribe, give or administer any drug or medicine for the use of any other person.

(3) Offer or undertake to perform any surgical operation upon any person.

(+) *CRITERION 2:*
Pain management is part of medical practice

(4) Offer or undertake to diagnose, cure or treat in any manner, or by any means, methods, devices or instrumentalities, any disease, illness, pain, wound, fracture, infirmity, deformity, defect or abnormal physical or mental condition of any person.

(5) Except as provided in ORS 677.060, append the letters "M.D." or "D.O." to the name of the person, or use the words "Doctor," "Physician," "Surgeon," or any abbreviation or combination thereof, or any letters or words of similar import in connection with the name of the person, or any trade name in which the person is interested, in the conduct of any occupation or profession pertaining to the diagnosis or treatment of human diseases or conditions mentioned in this section.

ORS § 677.228

677.228. Automatic lapse of license for failure to pay registration fee or report change of location; reinstatement.

(1) A person's license to practice under this chapter automatically lapses if the licensee fails to:

(a) Pay the registration fee as required by rule of the Board of Medical Examiners for the State of Oregon.

(b) Notify the board of a change of location not later than the 30th day after such change.

(c) Complete prior to payment of the registration fee described in paragraph (a) of this subsection, or provide documentation of previous completion of, if required by rule of the board:

(A) A pain management education program approved by the board and developed in conjunction with the Pain Management Commission established under ORS 409.500; or

(B) An equivalent pain management education program, as determined by the board.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (continuing education) to provide practitioners information/education about pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OREGON

STATUTES

Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

ORS § 677.470-677.480

677.470. Definitions for ORS 677.470 to 677.480.

As used in ORS 677.470 to 677.480:

(1) "Controlled substance" has the meaning given that term under ORS 475.005.

(2) "Health care professional" means a person licensed by a health professional regulatory board who is practicing within the scope of practice of that licensure and who is authorized to prescribe or administer controlled substances.

(3) "Health professional regulatory board" has the meaning given that term in ORS 676.440.

677.474. Administration of controlled substances for pain allowed; exceptions.

(+) *CRITERION 2:* ***Pain management is part of medical practice***

(1) Notwithstanding any other provision of this chapter and notwithstanding ORS 678.010 to 678.410 and ORS chapters 679 and 689, a health care professional may prescribe or administer controlled substances to a person in the course of treating that person for a diagnosed condition causing pain.

(+) *CRITERION 3:* ***Opioids are part of professional practice***

(+) *CRITERION 5:* ***Addresses fear of regulatory scrutiny***

(2) A health care professional shall not be subject to disciplinary action by a health professional regulatory board for prescribing or administering controlled substances in the course of treatment of a person for pain with the goal of controlling the patient's pain for the duration of the pain.

(3) Subsections (1) and (2) of this section do not apply to:

(a) A health care professional's treatment of a person for chemical dependency resulting from the use of controlled substances;

(b) The prescription or administration of controlled substances to a person the health care professional knows to be using the controlled substances for nontherapeutic purposes;

(c) The prescription or administration of controlled substances for the purpose of terminating the life of a person having pain, except as allowed under ORS 127.800 to 127.897; or

(d) The prescription or administration of a substance that is not a controlled substance approved by the United States Food and Drug Administration for pain relief.

(4) Subsection (2) of this section does not exempt the governing body of any hospital or other medical facility from the requirements of ORS 441.055.

677.480. Discipline.

ORS 677.474 does not prohibit a health professional regulatory board from placing on probation or denying, revoking, limiting or suspending the license of any health care professional who does any of the following:

(1) Prescribes or administers a controlled substance or treatment that is nontherapeutic in nature or nontherapeutic as administered or prescribed or that is administered or prescribed for a nontherapeutic purpose.

(2) Fails to keep a complete and accurate record of controlled substance purchases, dispensing and disposal as required by the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91-513), other federal law or ORS 475.005 to 475.285 and 475.840 to 475.980.

(3) Prescribes controlled substances without a legitimate medical purpose.

(4) Prescribes, administers or dispenses controlled substances in a manner detrimental to the best interest of the public.

(5) Prescribes, administers or dispenses a controlled substance in a manner prohibited under ORS 475.005 to 475.285 or 475.840 to 475.980.(6) Falsifies prescription information, including, but not limited to, the identity of the recipient.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

ORS § 689.005

689.005. Definitions.

As used in this chapter:

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(28) "Practitioner" means a person licensed and operating within the scope of such license to prescribe, dispense, conduct research with respect to or administer drugs in the course of professional practice or research:

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ORS § 689.285

689.285. Continuing pharmacy education; rules; fees.

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(3) In accordance with applicable provisions of ORS chapter 183, the board shall make reasonable rules:

(a) Prescribing the procedure and criteria for approval of continuing pharmacy education programs, including the number of hours of courses of study necessary to constitute a continuing pharmacy education unit and the number of continuing pharmacy education units required annually for renewal of a pharmacist license.

(b) Prescribing the scope of the examinations given by the board including grading procedures.

(c) Prescribing the content of the form to be submitted to the board certifying completion of an approved continuing pharmacy education program.

(d) Necessary to carry out the provisions of this chapter.

(e) Prescribing the completion of:
(A) A pain management education program approved by the board and developed in conjunction with the Pain Management Commission established under ORS 409.500; or
(B) An equivalent pain management education program, as determined by the board.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (continuing education) to provide practitioners information/education about pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

Or. Admin. R. 847-010-0100

847-010-0100 Mandatory Pain Management Education

(1) All licensees of the Board of Medical Examiners, except the licensees listed in section (2) of this rule, will complete mandatory continuing medical education (CME) in the subjects of pain management and/or the treatment of terminally ill and dying patients as follows:

(a) A one-hour pain management course specific to Oregon provided by the Pain Management Commission of the Department of Human Services; and

(b) A minimum of 6 (six) continuing medical education credit hours in the subjects of pain management and/or the treatment of terminally ill and dying patients. Any combination of CME coursework focusing on pain management and/or treatment of terminally ill and dying patients may be used to fulfill this requirement.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Or. Admin. R. 855-021-0016

855-021-0016 Continuing Education in Pain Management

(1) A pharmacist licensed under these rules must complete seven hours of continuing education in pain management as detailed in the following sub-sections. This is a one-time requirement:

(a) A one-hour pain management course, specific to Oregon, provided by the Pain Management Commission of the Oregon Department of Human Services; and

(b) A minimum of six hours of continuing education in pain management. This requirement may be fulfilled by any combination of continuing education coursework focusing on pain management including but not limited to the treatment of terminally ill and dying patients, and those with chronic, non-malignant pain.

(2) A licensee must complete the required continuing education within 24 months of their first license renewal after January 2, 2006.

(3) A licensee must retain for three years, documentation showing they have met the requirement of this rule, and must provide this documentation if requested by the Board.

(4) The pain management continuing education required under this rule shall count towards the 1.5 continuing pharmacy education units required under *OAR 855-021-0005*, in the license cycle in which the pain management continuing education is completed. Any portion of this continuing education may count towards the requirement in *OAR 855-021-0010(1)(a)* for 11 hours continuing education in therapeutics.

Or. Admin. R. 855-041-0173

855-041-0173 Definitions

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(9) "Practitioner" means a person licensed and operating within the scope of such license to prescribe and dispense, conduct research with respect to or administer drugs in the course of professional practice or research:

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

INTRACTABLE PAIN AND PAIN MANAGEMENT

BME STATEMENT OF PHILOSOPHY ON PAIN MANAGEMENT

The BME urges the use of effective pain control for all patients, irrespective of the etiology of their pain. This includes, but is not limited to, pain derived from malignancies, acute pain resulting from injuries, acute illnesses or invasive procedures and chronic pain of diverse etiology. Management of pain is considered to be within the scope of practice of most physicians. It is the expectation of the Board that physicians will be knowledgeable or become knowledgeable in treatment of pain for problems that are within their scope of practice.

Physicians choose not to provide pain care to patients for the following reasons: 1) concern about causing addiction; 2) lack of knowledge about pain management techniques and pain medication pharmacology; 3) fear of scrutiny and discipline by regulatory agencies; 4) challenges in determining the appropriate treatment; 5) inadequate compensation. The Board does not consider any of the reasons above to be legitimate excuses for a physician to exclude treatment of pain from their clinical practice. The Board expects that physicians will treat pain within the scope of their practice or refer when appropriate.

The treatment of acute pain caused by injuries, acute illnesses or interventional procedures requires aggressive management and frequent feedback from the patient regarding the adequacy of the pain control prescribed. The potential for addiction is very low when short courses of opioids are used to treat acute, self -limited pain. Skillful pain management techniques, including oral, parenteral and, when available, regional pain management techniques can achieve maximum patient comfort and may reduce the total amount of opioids required. The BME encourages physicians to become well informed in acute pain management and to hone their skills in the latest techniques for control of these acute, self-limited episodes of pain.

Management of the patient with a chronic pain syndrome requires different techniques but a similar degree of skill. In 1995, the Oregon Legislative Assembly passed ORS 677.470-485, commonly referred to as the Intractable Pain Act. This act allows a physician to prescribe or administer controlled substances to a patient diagnosed with a condition causing intractable pain without fear of sanction from the Board of Medical Examiners, so long as that physician complies with the provisions of this statute. Both this statute and its facilitating Oregon Administrative Rule (847-030-0015), as revised in 2004, assure that patients with chronic pain syndromes: (1) receive careful assessment, documentation, and management of the pain; (2) are informed of the risk of taking the controlled substances used in the course of their treatment; and 3) acknowledge receipt of this information by signing the approved material risk form*. Although the 2003 Legislature amended the Act to remove a stipulation that all chronic pain patients receive an "evaluation by one or more physicians specializing in the treatment of the body area, system or organ perceived as the source of the pain", the BME notes that the accepted standard of care includes such consultations (evaluations) when the diagnosis or appropriate treatment is uncertain or when the current treatment is not producing expected results.

Physicians should make every effort to relieve the pain and suffering of their terminally ill and dying patients. The BME believes this effort is the physician's primary obligation to these patients. Pain control in terminally ill/dying patients may require doses of opioids well above the usual amounts administered intermittently or continually. The natural dying process may involve declining blood pressures, decreasing respirations and altered levels of consciousness. When these patients continue to experience pain, opioids should not be withheld on the basis of physiologic parameters or from fear of hastening death.

Appropriate management of all of these types of pain is the treating physician's responsibility. Although there is often a significant amount of latitude regarding the amount of medication required for control of the pain, the Board considers undertreatment as well as overtreatment to be below the standard of care.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Pharmacy Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Treatment and Management of Pain

Healthcare leaders and patient advocates have come together in legislatively mandated pain commission to work toward providing well managed and adequate pain control to the citizens of Oregon. Involvement with The Oregon Pain Commission has prompted the Board of Pharmacy to take a leadership role in promoting the effective management of pain for the state's citizens. The mission of the Oregon Board of Pharmacy is to promote, preserve and protect the public health, safety and welfare by regulating the practice of pharmacy and the distribution of drugs within and into the state. As a part of that endeavor, the Board strives to ensure that all Oregonians have access to appropriate pain relief. Appropriate and effective pain therapies, including the use of controlled substance medications, can greatly improve a patient's quality of life and reduce unnecessary morbidity and cost associated with inadequate treatment of pain.

Inadequate pain control, in some cases, may result from a lack of knowledge or understanding of proper pain management by health care professionals and patients. Under-treatment of pain can also be the result of fear or misunderstanding of the position of regulatory boards or law enforcement agencies regarding the use of controlled substances in the treatment and management of pain. This statement is intended to clarify the Board of Pharmacy's position regarding pain management in the practice of pharmacy.

The Oregon Board of Pharmacy recognizes that the use of controlled substances, including opioid analgesics, is often essential for the treatment and management of both acute and chronic pain of any origin. A pharmacist involved in the care of a patient undergoing treatment for pain should not fear disciplinary action from the board for dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose as defined in the state of Oregon. Pharmacists' involvement with pain management in the usual course of their professional practice should be based upon accepted scientific knowledge and sound clinical judgment.

The Board of Pharmacy also recognizes that controlled substances, by their nature, carry with them a risk of abuse or misuse. All health care professionals must remain alert to the fact that these drugs are subject to abuse and that some people will seek them for inappropriate uses. Care must be taken to balance this risk with the desired outcome of effective pain control for all who are in need.

Dispensing of controlled substances for the treatment of pain must be based upon a valid prescription issued within currently accepted standards. All pharmacists are encouraged to increase their knowledge of current medical standards for the treatment of pain and develop effective strategies for delivering pharmaceutical care to patients suffering with pain. Pharmacists should actively participate on the health care team by providing expertise to the patient, physician, nurse and hospice provider or other care giver. As a member of the health care team, pharmacists can contribute to positive therapeutic outcomes for patients suffering from pain and can reduce the potential for drug abuse. Detailed documentation of the patient's medical condition and clinical response to treatment provides the strongest foundation for providing optimal patient care.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Oregon Pain Management Commission Joint Statement on Pain Management

This statement is intended to join Oregon Healthcare Boards, professionals and interested parties in a commitment to improve the pain management services of all Oregon citizens. Towards this end, the undersigned groups issue the following joint statement:

Inadequate pain relief is a serious public health problem in the United States. Estimates of Americans suffering from chronic pain range from 20%-30% of the population. The physical, psychological, emotional and behavioral effects of under treated pain are serious and wide-ranging. Pain continues to be undertreated. This causes unnecessary suffering and reduced function and quality of life in people with pain as well as increased healthcare utilization and lost workforce productivity.

Several reasons have been identified as barriers to effective pain treatment including: lack of knowledge of healthcare standards and guidelines, lack of reimbursement for multidisciplinary pain care, fear of sanctions by regulatory boards or law enforcement agencies, lack of familiarity of regulatory agencies and misunderstanding of addiction, tolerance and physical dependence.

To effectively assist patients with the effective management of pain, all Oregon healthcare professionals should, within their scope of practice:

- Routinely assess all patients for pain. All pain should be evaluated with a complete history and physical with laboratory and diagnostic tests when indicated
- Work with a multidisciplinary team to develop and implement a comprehensive treatment plan utilizing appropriate pharmacological and non-pharmacological interventions for treatment of pain and suffering
- Regularly re-evaluate the effectiveness of the treatment plan and adjust as needed
- Document the complete assessment and plan of care in a clear, consistent and accurate manner
- Treat side effects
- Be mindful of the risks of addiction and diversion of controlled substances and minimize risks using an opioid treatment plan. Recognize that people with chemical dependency also deserve to have pain effectively treated and that opioids may be a part of treatment
- Refer and consult with specialists as necessary
- Comply with all state and federal laws and encourage changes to promote improved pain management

A licensed practitioner involved in the care of a person in pain should not fear disciplinary action from their respective licensing board for prescribing or dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose as defined by the State of Oregon, based on accepted scientific knowledge and sound clinical judgment.

All Oregon practitioners are encouraged to increase their knowledge of current guidelines and standards for the treatment of pain, develop effective strategies for delivering effective care to patients suffering from pain and actively participate in the healthcare team providing expertise to the patient. By working in a team, optimal care can be provided while striving to reduce the potential for drug abuse. Detailed and complete documentation of the patient's assessment and treatment response provides the foundation for optimal patient care.

The Pain Management Commission's Joint Statement on Pain Management is supported by the following licensing boards and professional organizations:

Board of Chiropractic Examiners; Board of Psychologist Examiners; Board of Medical Examiners; Board of Nursing; Physical Therapist Licensing Board; Occupational Therapy Licensing Board; Board of Naturopathic Examiners; Board of Dentistry; Board of Pharmacy and Board of Medical Examiners-Acupuncture Program.

Others endorsing the statement are the Oregon Acupuncture Association; Oregon Psychological Association; Oregon State Pharmacy Association; Pain Society of Oregon; Oregon Hospice Association; Leukemia and Lymphoma Society; Oregon Academy of Family Physicians; Oregon Medical Directors Association; Oregon Geriatrics Society; Oregon Society of Physician Assistants; Oregon Health Care Association; and the Oregon Alliance of Senior and Health Services.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Identifies numerous important barriers to access to appropriate pain relief.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pain Management Commission

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

ORS § 409.500 – 409.570

409.500. Pain Management Commission established; duties; staffing.

(1) The Pain Management Commission is established within the Department of Human Services. The commission shall:

(a) Develop pain management recommendations;

(b) Develop ways to improve pain management services through research, policy analysis and model projects; and

(c) Represent the concerns of patients in Oregon on issues of pain management to the Governor and the Legislative Assembly.

(2) The pain management coordinator of the Department of Human Services shall serve as staff to the commission.

409.510. Additional duties of commission.

The Pain Management Commission shall:

(1) Develop a pain management education program curriculum and update it biennially;

(2) Provide health professional regulatory boards and other health boards, committees or task forces with the curriculum;

(3) Work with health professional regulatory boards and other health boards, committees or task forces to develop approved pain management education programs as required; and

(4)(a) Review the pain management curricula of educational institutions in this state that provide post-secondary education or training for persons required by ORS 409.560 to complete a pain management education program. The commission shall make recommendations about legislation needed to ensure that adequate information about pain management is included in the curricula reviewed and shall report its findings to the Legislative Assembly in the manner required by ORS 192.245 by January 1 of each odd-numbered year.

(b) As used in this subsection, "post-secondary educational institution" has the meaning given that term in ORS 348.105.

409.560. Pain management education required of certain licensed health care professionals; duties of Oregon Medical Board; rules.

(1) A physician assistant licensed under ORS chapter 677, a nurse licensed under ORS chapter 678, a psychologist licensed under ORS 675.010 to 675.150, a chiropractic physician licensed under ORS chapter 684, a naturopath licensed under ORS chapter 685, an acupuncturist licensed under ORS 677.759, a pharmacist licensed under ORS chapter 689, a dentist licensed under ORS chapter 679, an occupational therapist licensed under ORS 675.210 to 675.340 and a physical therapist licensed under ORS 688.010 to 688.201 must complete one pain management education program described under ORS 409.510.

(2) The Oregon Medical Board, in consultation with the Pain Management Commission, shall identify by rule physicians licensed under ORS chapter 677 who, on an ongoing basis, treat patients in chronic or terminal pain and who must complete one pain management education program established under ORS 409.510. The board may identify by rule circumstances under which the requirement under this section may be waived.

409.570. Rules.

In accordance with applicable provisions of ORS chapter 183, the Pain Management Commission may adopt rules necessary to implement *ORS 409.500* to *409.570*.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (Pain Management Commission) to improve pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (education program curriculum) to provide practitioners information/education about pain management, as well as to review the curricula that is created.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (rules) for the Pain Management Commission to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

STATUTES

Professional Practice

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

ORS § 676.440

676.440. Duty of health professional regulatory boards to encourage multidisciplinary pain management services.

(1) Health professional regulatory boards shall encourage the development of state-of-the-art multidisciplinary pain management services and the availability of these services to the public.

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(+) *CRITERION 4:*
Encourages pain management

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospital Licensing Procedures

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Or. Admin. R. 333-500-0056

333-500-0056 Annual Random Audits

The department shall conduct an annual random audit of not less than seven percent of all hospitals in the state to verify compliance with the requirements of *ORS 441.162*, *441.166* and *441.192*, and *OAR 333-510-0045*. Surveys made by private accrediting organizations may not be used in lieu of the audit required by this rule.

(1) The audit shall include, at a minimum, confidential interviews of administrative and clinical staff, a review of the written staffing plan, the actual nursing staff scheduled and working as compared with the plan, all applicable committee meeting minutes, any reports filed by clinical staff regarding staffing inadequacy, and any patient outcome data including, but not limited to, nurse sensitive patient outcome data (e.g. nosocomial infections, pressure ulcers, patients' falls, patient satisfaction with pain management, medication errors).

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (random audits) for hospitals to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Pain Management Commission

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Or. Admin. R. 407-020-0000

407-020-0000 Purpose

The Pain Management Commission was established within the Department of Human Services for the purpose of developing pain management educational programs, recommendations and curriculum; representing patient concerns to the Governor and Legislative Assembly; and creating ways to improve pain management in Oregon through research, policy analysis, and model projects. In addition, the Pain Management Commission is charged with developing a specific pain management educational program for required completion by health care professionals under specified Licensing Boards.

Or. Admin. R. 407-020-0015

407-020-0015 Pain Management Education Program Requirements

(1) Licensed health care professionals must complete a pain management education program in order to improve the care and treatment of individuals with painful conditions. The program includes:

(a) Six accredited hours of continuing education in pain management, end of life care or a combination of both; and

(b) The web-based training offered by the Commission.

(2) The pain management education program is a one time requirement that must be obtained:

(a) Within twenty-four months of January 2, 2006, which would include approved trainings acquired between January 2, 2004 and January 2, 2008; or

(b) Within twenty-four months of the first renewal of the individual's license after January 2, 2006.

Example: If an individual's license expired on December 15, 2005 then again on December 15, 2007, the individual may have obtained training to fulfill this requirement as far back as January 2, 2004 (2)(a) or they may obtain training through December 15, 2009 (2)(b) to comply with this requirement.

(3) For out of state health care professionals obtaining Oregon licensure or newly licensed health care professionals within Oregon, the pain management education program must be completed within 24 months of their first license renewal.

Example: If an individual becomes newly licensed in Oregon on June 15, 2009, their first renewal will be June 15, 2011. The individual may obtain their training from June 15, 2009 through June 15, 2013 (2)(b) to comply with this requirement.

(4) If the licensing board for a licensed health care professional adopts, by rule, a pain management education program with topics substantially similar to the topics in the Commission's curriculum, that program satisfies this rule for the continuing education portion of the requirement, as long as the total number of hours is the same.

(5) The Commission shall update its curriculum every two years.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (pain management curriculum) to provide practitioners information/education about pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (continuing education) to provide practitioners information/education about pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Personal Care Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for health care facilities to ensure that pain management is an essential part of patient care.

Or. Admin. R. 411-034-0070

411-034-0070 Service Assessment, Authorization, and Monitoring

(1) Case Manager Responsibilities:
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(f) The Case Manager may refer a Contract RN where available, for nursing assessment and monitoring when it appears the individual needs assistance to manage health care needs and may need delegated nursing tasks, nurse assessment and consultation, teaching, or services requiring RN monitoring.

(A) Indicators of the need for Contract RN assessment and monitoring include:
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(vi) Pain issues;
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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

PA

PENNSYLVANIA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 35. Health and Safety;
  Chapter 6. The Controlled Substance, Drug, Device, and Cosmetic Act
  Chapter 6B. Drugs, Poisons and Dangerous Substances

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 63. Professions and Occupations (State Licensed); Chapter 12. Physicians and Surgeons

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Title 63. Professions and Occupations (State Licensed); Chapter 9. Osteopaths

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 63. Professions and Occupations (State Licensed); Chapter 11. Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 28. Health and Safety; Part III. Prevention of Disease; Chapter 25. Controlled Substances, Drugs, Devices, and Cosmetics

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 49. Professional and Vocational Standards; Part 1. Department of State; Subpart A. Professional and Occupational Affairs;
  Chapter 16. State Board of Medicine – General Provisions
  Chapter 17. State Board of Medicine – Medical Doctors

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Title 49. Professional and Vocational Standards; Part 1. Department of State; Subpart A. Professional and Occupational Affairs; Chapter 25. State Board of Osteopathic Medicine

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 49. Professional and Vocational Standards; Part 1. Department of State; Subpart A. Professional and Occupational Affairs; Chapter 27. State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Pennsylvania State Board of Medicine. *Guidelines for the Use of Controlled Substances in the Treatment of Pain. Pennsylvania State Board of Medicine Bulletin*. Winter, pp. 4-5, 1998-1999. Adopted: October 20, 1998.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HEALTH FACILITIES

  Title 28. Health and Safety; Part IV. Health Facilities; Subpart F. Ambulatory Surgical Facilities; Chapter 553. Ownership, Governance and Management; Admission, Transfer and Discharge

PA

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Health Facilities								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances						●		
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Health Facilities[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

PENNSYLVANIA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

35 P.S. § 780-102

[P.S.] § 780-102. Definitions

(a) The definitions contained and used in the "Pennsylvania Drug and Alcohol Abuse Control Act" shall also apply for purposes of this act.

(b) As used in this act:

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"DRUG DEPENDENT PERSON" means a person who is using a drug, controlled substance or alcohol, and who is in a state of psychic or physical dependence, or both, arising from administration of that drug, controlled substance or alcohol on a continuing basis. Such dependence is characterized by behavioral and other responses which include a strong compulsion to take the drug, controlled substance or alcohol on a continuous basis in order to experience its psychic effects, or to avoid the discomfort of its absence. This definition shall include those persons commonly known as "drug addicts."

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"PRACTITIONER" means: (i) a physician, osteopath, dentist, veterinarian, pharmacist, podiatrist, nurse, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance, other drug or device in the course of professional practice or research in the Commonwealth of Pennsylvania; (ii) a pharmacy, hospital, clinic or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance, other drug or device in the course of professional practice or research in the Commonwealth of Pennsylvania.

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(-) *CRITERION 11: Physical dependence or analgesic tolerance confused with "addiction"*

(+) *CRITERION 3: Opioids are part of professional practice*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

PENNSYLVANIA

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

28 Pa. Code § 25.131

§ 25.131. Every dispensing practitioner

Every pharmacy shall, at the end of each month, on forms issued for this purpose by the Office of the Attorney General of the Commonwealth, provide the Office of the Attorney General of the Commonwealth with the name of each person to whom a drug or preparation, which is classified by the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C.A. § 3801 and the act as a controlled substance in Schedule II, was sold, dispensed, distributed or given away, except when used in anesthetic procedures, together with such other information as may be required, under the act.

(-) *CRITERION 14: Undue prescription requirements*

COMMENT: This provision requires reporting. Submission to the Attorney General of the names of all pain patients who receive Schedule II pain medications suggests that there is something about these drugs or these patients that requires scrutiny by law enforcement, which may reinforce concerns about regulatory scrutiny.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

PENNSYLVANIA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES IN THE TREATMENT OF PAIN

Section I: Preamble

The Pennsylvania State Board of Medicine recognizes that principles of quality medical practice dictate that the citizens of the Commonwealth have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as to reduce the morbidity and costs associated with untreated or inappropriately treated pain. The board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as legal requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in an inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management. The board has found that these guidelines are consistent with the board's regulations pertaining to prescribing, administering and dispensing controlled substances located at 49 Pa. Code §16.92.

The board recognizes that controlled substances, including opioid analgesics, are essential in the treatment of acute pain due to trauma, surgery and chronic pain due to cancer and other progressive diseases. Physicians are referred to the U.S. Agency for Health Care Policy and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain.

The medical management of pain should be based upon current knowledge and research and includes the use of both pharmaceutical and non-pharmaceutical modalities. Pain should be assessed and treated promptly and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The State Board of Medicine is obligated under the law to protect the public health and safety. The board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate and non-medical uses.

Physicians should not fear disciplinary action from the board or other state regulatory or enforcement agency for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain and in compliance of applicable state or federal law.

The board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to treat the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, physiological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the board considers to be within the boundaries of professional practice.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

Section II: Guidelines
The board has found that the following guidelines indicate acceptable standards of practice when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical report. The medical record should document the nature and intensity of the pain, evaluate underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, significant other(s) or guardian. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities including (1) urine/serum medication levels screening when requested (2) number and frequency of all prescription refills and (3) reasons for which drug therapy may be discontinued (i.e., violation of agreement).

4. Periodic Review

At reasonable intervals based upon the individual circumstance of the patient, the physician should review the course of opioid treatment and any new information about the etiology of the pain. Continuation or modification of opioid therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function, such as ability to work, need of health care resources, activities of daily living and quality of social life. If reasonable treatment goals are not being achieved despite medication adjustments, the physician should monitor patient compliance in medication usage and related treatment plans.

5. Consultation

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement poses a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder require extra care, monitoring, documentation and consultation with a referral to an expert in the management of such patients.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

6. Medical Records

The physician should keep accurate and complete records to include (1) the medical history and physical examination; (2) diagnostic, therapeutic and laboratory results; (3) evaluations and consultations; (4) treatment objectives; (5) discussion of risks and benefits; (6) treatments; (7) medications (including date, type, dosage and quantity prescribed); (8) instructions and agreements; and (9) periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance with Controlled Substances Laws and Regulations

To prescribe controlled substances, the physician must be licensed in the state, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the regulations of the board for specific rules governing issuance of controlled substances prescriptions as well as applicable state regulations.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

PENNSYLVANIA

REGULATIONS

Health Facilities

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for Ambulatory Surgical Facilities to ensure that pain management is an essential part of discharge criteria.

28 Pa. Code § 553.25

§ 553.25. Discharge criteria

A patient may only be discharged from an ASF if the following physical status criteria are met:

(1) *Vital signs.* Blood pressure, heart rate, temperature and respiratory rate are within the normal range for the patient's age or at preoperative levels for that patient.

(2) *Activity.* The patient has regained preoperative mobility without assistance or syncope, or function at the patient's usual level considering limitations imposed by the surgical procedure.

(3) *Mental status.* The patient is awake, alert or functions at the patient's preoperative mental status.

(4) *Pain.* The patient's pain can be effectively controlled with medication.

(5) *Bleeding.* Bleeding is controlled and consistent with that expected from the surgical procedure.

(6) *Nausea/vomiting.* Minimal nausea or vomiting is controlled and consistent with that expected from the surgical procedure.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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RHODE ISLAND

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 21. Food and Drugs; Chapter 28. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Title 5. Businesses and Professions; Chapter 37. Board of Medical Licensure and Discipline

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Title 5. Businesses and Professions; Chapter 37.4. Intractable Pain Treatment

- PAIN ASSESSMENT ACT (*Part of Medical Practice Act*)
  Title 5. Businesses and Professions; Chapter 37.6. Pain Assessment Act

- OSTEOPATHIC PRACTICE ACT (*Repealed*)
  Title 5. Businesses and Professions; Chapter 36. Osteopaths

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 5. Businesses and Professions; Chapter 19.1. Pharmacies

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Agency 14. Department of Health; Sub-Agency 060. Food and Drug Control Division

- MEDICAL BOARD REGULATIONS
  Agency 14. Department of Health; Sub-Agency 140. Office of Health Professionals Regulation; Chapter 031. Licensure and Discipline of Physicians

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Agency 14. Department of Health; Sub-Agency 130. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Rhode Island Board of Medical Licensure and Discipline. *Guidelines for Long-Term Pain Management*. *Newsletter of the Rhode Island Board of Medical Licensure and Discipline*. Summer, p. 2, 1995. Adopted: May 10, 1995.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- ASSISTED SUICIDE
  Title 11. Criminal Offenses; Chapter 60. Assisted Suicide

- DRUG ABUSE CONTROL
  Title 21. Food and Drugs; Chapter 28.2. Drug Abuse Control

- LICENSING OF HEALTH CARE FACILITIES
  Title 23. Health and Safety; Chapter 17. Licensing of Health Care Facilities

- RIGHTS OF NURSING HOME PATIENTS
  Title 23. Health and Safety; Chapter 17.5. Rights of Nursing Home Patients

- PROFESSIONAL PRACTICE
  Agency 14. Department of Health; Sub-Agency 000. General

- LICENSING HOSPICE CARE
  Agency14. Department of Health; Sub-Agency 090. Health Facilities, Licensure, Construction; Chapter 017. Licensing Hospice Care

- LICENSING REHABILITATION HOSPITAL CENTERS
  Agency14. Department of Health; Sub-Agency 090. Health Facilities, Licensure, Construction; Chapter 018. Licensing Rehabilitation Hospital Centers

- LICENSING OF NURSING FACILITIES
  Agency14. Department of Health; Sub-Agency 090. Health Facilities, Licensure, Construction; Chapter 023. Licensing of Nursing Facilities

Note: Rhode Island's Uniform Controlled Substances Act continues to reference the duplicate prescription program that was repealed in 1997; although not considered a barrier to practice, efforts should be made to remove from state law all references to this vestigial policy.

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act		●						
Intractable Pain Treatment Act			●		●			●
Pain Assessment Act								●
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances								●
Medical Board		●						●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline								●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Assisted Suicide								●
Drug Abuse Control								●
Licensing of Health care Facilities								●
Rights of Nursing Home Patients								●
Professional Practice								●
Licensing Hospice Care								●
Licensing Rehabilitation Hospital Centers								●
Licensing of Nursing Facilities								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act				●				
Medical Practice Act[1]								
Intractable Pain Treatment Act[1]								
Pain Assessment Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline				●				
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Assisted Suicide[1]								
Drug Abuse Control[1]								
Licensing of Health care Facilities[1]								
Rights of Nursing Home Patients[1]								
Professional Practice[1]								
Licensing Hospice Care[1]								
Licensing Rehabilitation Hospital Centers[1]								
Licensing of Nursing Facilities[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

RHODE ISLAND

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

R.I. Gen. Laws § 21-28-1.02

§ 21-28-1.02. Definitions

Unless the context otherwise requires, the words and phrases as defined in this section are used in this chapter in the sense given them in the following definitions:

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(37) "Practitioner" means:

(i) A physician, osteopath, dentist, chiropodist, veterinarian, scientific investigator, or other person licensed, registered or permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

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(+) *CRITERION 3:*
Opioids are part of professional practice

R.I. Gen. Laws § 21-28-3.18

§ 21-28-3.18. Prescriptions

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(m) Prescriptions for controlled substances as found in schedule II may be written for up to a 30-day supply, with a maximum of two hundred and fifty (250) dosage units, as determined by the prescriber's directions for use of the medication. In no event shall more than a 30-days' supply, up to a maximum of two hundred and fifty (250) dosage units, be dispensed at one time.

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(-) *CRITERION 12:*
Medical decisions are restricted

***CATEGORY C*:**
Restrictions regarding quantity prescribed or dispensed

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

R.I. Gen. Laws § 5-37-1

§ 5-37-1. Definitions

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(14) "Practice of medicine" shall include the practice of allopathic and osteopathic medicine. Any person shall be regarded as practicing medicine within the meaning of this chapter who holds himself or herself out as being able to diagnose, treat, operate, or prescribe for any person ill or alleged to be ill with disease, pain, injury, deformity or abnormal physical or mental condition, or who shall either profess to heal, offer or undertake, by any means or method to diagnose, treat, operate, or prescribe for any person for disease, pain, injury, deformity or physical or mental condition. In addition, one who attaches the title, M.D., physician, surgeon, D.O., osteopathic physician and surgeon, or any other similar word or words or abbreviation to his or her name indicating that he or she is engaged in the treatment or diagnosis of the diseases, injuries or conditions of persons shall be held to be engaged in the practice of medicine.

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(+) *CRITERION 2:*
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

R.I. Gen. Laws § 5-37.4-1 – § 5-37.4-3

§ 5-37.4-1. Title

This chapter shall be known and may be cited as the "Intractable Pain Treatment Act".

§ 5-37.4-2. Definitions

For purposes of this chapter:

(1) "Director" means the director of the department of health of the state of Rhode Island.

(2) "Intractable pain" means a pain state that persists beyond the usual course of an acute disease or healing of an injury or results from a chronic disease or condition that causes continuous or intermittent pain over a period of months or years.

(+) *CRITERION 3:*
Opioids are part of professional practice

(3) "Practitioner" means health care professionals licensed to distribute, dispense, or administer controlled substances in the course of professional practice as defined in § 21-28-1.02(36).

(4) "Therapeutic purpose" means the use of controlled substances for the treatment of pain in appropriate doses as indicated by the patient's medical record. Any other use is nontherapeutic.

§ 5-37.4-3. Controlled substances

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(a) A practitioner may prescribe, administer, or dispense controlled substances not prohibited by law for a therapeutic purpose to a person diagnosed and treated by a practitioner for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical records. No practitioner shall be subject to disciplinary action by the board solely for prescribing, administering, or dispensing controlled substances when prescribed, administered, or dispensed for a therapeutic purpose for a person diagnosed and treated by a practitioner for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical records.

(b) The provisions of subsection (a) of this section do not apply to those persons being treated by a practitioner for chemical dependency because of their use of controlled substances not related to the therapeutic purposes of treatment of intractable pain.

(c) The provisions of subsection (a) of this section provide no authority to a practitioner to prescribe, administer, or dispense controlled substances to a person the practitioner knows or should know to be using the prescribed, administered, or dispensed controlled substance non-therapeutically.

(d) Drug dependency or the possibility of drug dependency in and of itself is not a reason to withhold or prohibit prescribing, administering, or dispensing controlled substances for the therapeutic purpose of treatment of a person for intractable pain, nor shall dependency relating solely to this prescribing, administering, or dispensing subject a practitioner to disciplinary action by the director.

(e) Nothing in this section shall deny the right of the director to deny, revoke, or suspend the license of any practitioner or discipline any practitioner who:

(1) Prescribes, administers, or dispenses a controlled substance that is nontherapeutic in nature or nontherapeutic in the manner in which it is prescribed, administered, or dispensed, or fails to keep complete and accurate on-going records of the diagnosis and treatment plan;

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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(2) Fails to keep complete and accurate records of controlled substances received, prescribed, dispensed and administered, and disposal of drugs as required by law or of controlled substances scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970, *21 U.S.C. § 801,* et seq. A practitioner shall keep records of controlled substances received, prescribed, dispensed and administered, and disposal of these drugs shall include the date of receipt of the drugs, the sale or disposal of the drugs by the practitioner, the name and address of the person receiving the drugs, and the reason for the disposal or the dispensing of the drugs to the person;

(3) Writes false or fictitious prescriptions for controlled substances as prohibited by law, or for controlled substances scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970, *21 U.S.C § 801,* et seq.; or

(4) Prescribes, administers, or dispenses in a manner which is inconsistent with provisions of the law, or the Comprehensive Drug Abuse Prevention and Control Act of 1970, *21 U.S.C. § 801,* et seq., any controlled substance.

(f) A practitioner may administer a controlled substance prescribed by a practitioner and not prohibited by law for a therapeutic purpose to a person diagnosed and treated by a practitioner for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical records. No practitioner shall be subject to disciplinary action by the director solely for administering controlled substances when prescribed or dispensed for a therapeutic purpose for a person diagnosed and treated by a practitioner for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical records of the patient.

STATUTES

Pain Assessment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

R.I. Gen. Laws § 5-37.6-1 – § 5-37.6-8

§ 5-37.6-1. Short title

This chapter shall be known and may be cited as the "Pain Assessment Act."

§ 5-37.6-2. Findings

The general assembly finds and declares that:

(1) Pain affects quality of life, job performance and security;

(2) Nearly thirty percent (30%) of nursing home residents with daily pain were receiving no pain medication of any form;

(3) Pain untreated or under-treated adversely impacts the quality of life for patients;

(4) Up to ninety-five percent (95%) of terminally ill patients' pain can be relieved with adequate pain management; and

(5) Too many Rhode Islanders are suffering and dying in needless pain.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pain Assessment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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§ 5-37.6-3. Definitions

As used in this chapter, the following terms have the following meanings:

(1) "Assessment of pain" means the act of assessing an unpleasant sensation occurring in varying degrees of severity as a consequence of injury, disease, or emotional disorder;

(2) "Director" means the director of the department of health;

(3) "Health care facilities" is defined in the same manner as in § 23-17-2(6);

(4) "Health care provider" means any person licensed by this state to provide or lawfully providing health care services, including, but not limited to, a physician, dentist, optometrist, nurse, podiatrist, physical therapist, nurse practitioner or physician's assistant;

(5) "Person" means any individual, trust or estate, partnership, limited liability corporation, corporation (including associations, joint stock companies, and insurance companies), state, or political subdivision or instrumentality of a state;

(6) "Regular basis" means a procedure done on a customary, usual, normal, orderly, even, or symmetrical schedule.

§ 5-37.6-4. Pain assessment

(a) Health care facilities and health care providers shall conduct an assessment of pain experienced by a patient on a regular basis.

(b) The assessment of pain shall be noted in the patient's chart in a manner consistent with vital signs.

§ 5-37.6-5. Regulations

(a) *Promulgation by department.* The director of the department shall promulgate regulations relating to the assessment of pain requirements of this chapter.

(b) *Educational materials.* The director shall make available educational and informational materials concerning the assessment of pain to health care facilities and health care providers.

§ 5-37.6-6. Enforcement

The director of the department of health shall have the power to enforce the provisions of this chapter.

§ 5-37.6-7. Penalty

(a) Every person who shall willfully and continually violate the provisions of this chapter is subject to a fine up to one hundred dollars ($ 100) for a first violation and any other remedy provided for in the Rhode Island law.

(b) Every person who shall continuously violate this chapter is subject to a fine up to five hundred dollars ($ 500) for each subsequent violation in addition to any other remedy provided for in the Rhode Island law.

§ 5-37.6-8. Severability

If any provision of this chapter or any rule or regulation made under this chapter or the application of any provision of this chapter to any person or circumstance shall be held invalid by any court of competent jurisdiction, the remainder of the chapter, rule or regulation and the application of the provision to other persons or circumstances shall not be affected by that invalidity. The invalidity of any section or sections or parts of any section of this chapter shall not affect the validity of the remainder of this chapter and to this end the provisions of the chapter are declared to be severable.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for health care facilities to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (regulations) for the Department of Health to improve pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (educational materials) to provide practitioners information/education about pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

CRIR 14-060-020

14 060 020 Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II and III

INTRODUCTION

These Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II and III (R21-28-EDT) are promulgated pursuant to the authority set forth in sections 42-35 and 21-28-3.18 of the General Laws of Rhode Island, as amended. These regulations are established for the purpose of defining minimum standards for the establishment of an electronic data transfer system between the Department of Health and pharmacies in this state for schedules II and III controlled substances.

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Section 3.0 Data Collection

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3.3 The Department shall:

3.3.1 be authorized to provide data in the electronic prescription system to other regulatory, investigative or law enforcement agencies for disciplinary, civil, or criminal purposes, and for the purposes of educating practitioners in lieu of disciplinary, civil or criminal action.

3.3.2 be authorized to provide data to appropriate public or private entities for statistical, research, or educational purposes provided that the privacy and confidentiality of patients and patient information is not compromised.

3.3.3 in using the information for investigative or prosecutorial purposes, consider the nature of the prescriber's or dispenser's practice and the condition(s) for which the patient is being treated.

3.3.4 ensure the privacy and confidentiality of patients and shall ensure that patient information collected, recorded, transmitted, and stored in the prescription system is maintained in accordance with applicable state and federal laws, rules and regulations.

3.3.5 ensure that the EDT program does not infringe on the legal use of any schedule II or III controlled substance.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for the Department of Health to consider case-specific details, such as the patient's diagnosis, when reviewing prescription monitoring program information used for investigations.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for the Department of Health to ensure that a prescription monitoring program does not interfere with the legitimate medical use of controlled substances, which represents the principle of Balance.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

CRIR 14-140-031

14 140 031 Licensure and Discipline of Physicians

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1.14 "Practice of Medicine", pursuant to section 5-37-1 (1) of the Act, shall include the practice of allopathic and osteopathic medicine. Any person shall be regarded as practicing medicine within the meaning of the act who holds himself or herself out as being able to diagnose, treat, operate, or prescribe for any person ill or alleged to be ill with disease, pain, injury, deformity or abnormal physical or mental condition, or who shall either profess to heal, offer or undertake, by any means or method, to diagnose, treat, operate, or prescribe for any person for disease, pain, injury, deformity or physical or mental condition. In addition, one who attaches the title M.D., physician, surgeon, D.O., osteopathic physician and surgeon, or any other similar word or words or abbreviation to his or her name indicating that he or she is engaged in the treatment or diagnosis of the diseases, injuries or conditions of persons shall be held to be engaged in the practice of medicine.

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Section 6.0 Continuing Education

6.1 Every physician licensed to practice allopathic or osteopathic medicine in Rhode Island under the provisions of the Act and the regulations herein, shall on or before the first day of June of every even-numbered year after 2004, on a biennial basis, earn a minimum of forty (40) hours of AMA category 1/AOA category 1a continuing medical education credits and shall document this to the Board.

6.2 The application shall include evidence satisfactory to the Board of completion of a prescribed program of continuing medical education established by the Board approved medical or osteopathic society. Participation by duly appointed members of the Board in regular Board meetings and investigating committee meetings shall be considered acceptable on an hours served basis in lieu of AMA category 1/AOA category 1a continuing medical education hours.

6.2.1 Said continuing medical education shall include a minimum of two (2) hours related to current information on any one or more of the following topics: universal precautions, infection control, modes of transmission, bioterrorism, OSHA, ethics, end-of-life education, palliative care, pain management, and other regulatory requirements.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management and palliative care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

GUIDELINES FOR LONG TERM PAIN MANAGEMENT

The Rhode Island Board of Medical Licensure and Discipline continues to see cases in which serious problems in the management of long-term intractable pain are encountered by patients and physicians. The board is aware of the perception that many physicians "under-treat" such patients based on a fear of "causing addiction"; on the other hand, we receive many allegations of the improper, sometimes illegal, "over-use" of controlled substances. The prescribing of controlled substances in every state is regulated by state and federal law. The Board is aware that there is a national problem relating to pain management. Accordingly, the Board has undertaken a review of guidelines adopted by various state medical boards (Colorado, Texas, New Jersey, Massachusetts and California) concerning the appropriate management of patients with long-term intractable pain. The Board of Medical Licensure and Discipline was most impressed with the guidelines that the State of California has released.

The California guidelines resulted from a state sponsored summit in which 120 health care practitioners, professional and public educators, representatives from professional schools and associations and health care consumers met to recommend solutions to legal, professional, and educational barriers to effective pain management. A report, Summit on Effective Pain Management: Removing Impediments to Appropriate Prescribing, was issued by the Governor of California. This comprehensive report was reviewed by the Board of Medical Licensure and Discipline as part of its decision to adopt the following guidelines to help the practicing physician dealing with this difficult problem.

GUIDELINES FOR LONG TERM PAIN MANAGEMENT

1. HISTORY/PHYSICAL EXAMINATION

A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function, substance abuse history, assessment of underlying or coexisting diseases or conditions, and should also include the presence of a recognized medical indication for the use of a controlled substance.

2. TREATMENT PLAN, OBJECTIVES

The treatment plan should state objectives by which treatment success can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician should tailor drug therapy to the individual medical needs of each patient. Several treatment modalities or a rehabilitation program may be necessary if the pain has differing etiologies or is associated with physical and psychosocial impairment.

3. INFORMED CONSENT

The physician should discuss the risks and benefits of the use of controlled substances with the patient, guardian or authorized representative. This discussion should be documented and signed by the patient, guardian or authorized representative.

4. PERIODIC REVIEW

The physician should periodically review the course of opioid treatment of the patient and any new information about the etiology of the pain. Continuation or modification of opioid therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient has not improved, the physician should assess the appropriateness of continued opioid treatment or trial of other modalities.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY B:
Mandated consultation

[CONTINUED]

5. CONSULTATION

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists, and may entail the use of agreements between the provider and the patient that specify the rules for medication use and consequences for misuse.

6. RECORDS

The physician should keep accurate and complete records according to items 1-5 above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, agreements with the patient, and periodic reviews.

7. COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS AND REGULATIONS

To prescribe controlled substances, the physician must be licensed appropriately in Rhode Island, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the General Laws of the State of Rhode Island relating to the Board of Medical Licensure and Discipline and the Division of Drug Control of the Rhode Island Department of Health.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

RHODE ISLAND

STATUTES

Assisted Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

R.I. Gen. Laws § 11-60-4

(a) A licensed health care professional who administers, prescribes, or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, does not violate the provision of this chapter unless the medications or procedures are knowingly administered, prescribed, or dispensed to cause death.

A licensed health care professional who withholds or withdraws a life-sustaining procedure in compliance with chapter 4.10 or title 23 does not violate the provisions of this chapter.

STATUTES

Drug Abuse Control

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

R.I. Gen. Laws § 21-28.2-1

§ 21-28.2-1. Definitions

Unless the context otherwise requires, the following terms shall be construed in this chapter to have the following meanings:

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(3) "Narcotic addict" means a person who is at the time of examination dependent upon opium, heroin, morphine, or any derivative or synthetic drug of that group or any other narcotic drug as defined in § 21-28-1.02, or a depressant or stimulant substance, or who by reason of the repeated use of any such drug is in imminent danger of becoming dependent upon opium, heroin, morphine, or any derivative or synthetic drug of that group, or any other narcotic drug as defined in § 21-28-1.02; or any person who is or has been so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his or her addiction; provided, that no person shall be deemed a narcotic addict solely by virtue of his or her taking of any of the drugs pursuant to a lawful prescription issued by a physician in the course of professional treatment for legitimate medical purposes.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Ensures that pain patients would not be labeled as a narcotic addict.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Licensing of Health Care Facilities

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for health care facilities to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

R.I. Gen. Laws § 23-17-19.1

§ 23-17-19.1. Rights of patients

Every health care facility licensed under this chapter shall observe the following standards and any other standards that may be prescribed in rules and regulations promulgated by the licensing agency with respect to each patient who utilizes the facility:

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(17) The patient shall have the right to have his or her pain assessed on a regular basis.

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STATUTES

Rights of Nursing Home Patients

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

R.I. Gen. Laws § 23-17.5-28

§ 23-17.5-28. Pain assessment

A patient shall have the right to have his or her pain assessed on a regular basis.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for nursing homes to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

RHODE ISLAND

REGULATIONS

Professional Practice Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

CRIR 14-000-029

14 000 029 Pain Assessment

INTRODUCTION

These rules and regulations are promulgated under the authority contained in Chapters 5-37.6 and 42-35 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting requirements relating to the assessment of pain by health care facilities and health care providers in Rhode Island.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for health care facilities and health care providers to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

REGULATIONS

Licensing Hospice Care

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospice facilities to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

CRIR 14-090-017

14 090 017. LICENSING HOSPICE CARE

Section 14.0 Minimum Services Required/Availability and Accessibility of Services.

14.1 Any service available through a hospice program shall be provided to patients/families, with the consent of the terminally ill patient and family.

14.2 Services that are to be provided directly through staff personnel of a hospice program shall include the following core services:

a) physician services (may include attending physicians' or certified registered nurse practitioners' services in accordance with section 17.1 herein);

b) nursing services;

c) social services;

d) counseling services, including spiritual counseling, when required;

e) pain assessment; and

f) availability of drugs and biologicals on a 24-hour basis.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Licensing Rehabilitation Hospital Centers

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

CRIR 14-090-018

14 090 018. LICENSING REHABILITATION HOSPITAL CENTERS

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Section 20.0 Plan of Care.

20.1 After initial assessment of patient rehabilitative needs, a written plan of care shall be established by the interdisciplinary team for each patient admitted to the center and at each level of care. Such plan shall designate the intensity of services required in relation to the disability and the individual's response to treatment and shall include provisions pertaining to:

(a) pertinent diagnosis and prognosis;

(b) identification of the intensity of patient care needs including the range of rehabilitation services required; the level of care required; the frequency of therapeutic services required; medications; management of discomfort and pain control; and other rehabilitative needs and prescribed therapies;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written plan of care) for rehabilitation hospital centers to ensure that pain management is an essential part of patient care.

REGULATIONS

Licensing of Nursing Facilities

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

CRIR 14-090-023

14 090 023 Licensing of Nursing Facilities

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Section 19.0 Rights of Residents.

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19.20 The resident shall have the right to have his or her pain assessed on a regular basis.

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Section 25.0 Selected Nursing Care Procedures.

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Pain Assessment

25.15 All health care providers licensed by this state to provide health care services and all health care facilities licensed under Chapter 23-17 of the Rhode Island General Laws, as amended, shall assess patient pain in accordance with the requirements of the Rules and Regulations Related to Pain Assessment (R5-37.6-PAIN) promulgated by the Department.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for nursing facilities to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

SC

SOUTH CAROLINA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 44. Health; Chapter 53. Poisons, Drugs and Other Controlled Substances; Article 3. Narcotics and Controlled Substances

- MEDICAL PRACTICE ACT
  Title 40. Professions and Occupations; Chapter 47. Physicians, Surgeons and Osteopaths

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 40. Professions and Occupations; Chapter 43. Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Chapter 61. Department of Health and Environmental Control; 61-4. Controlled Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Chapter 81. Department of Labor, Licensing and Regulation – State Board of Medical Examiners

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Chapter 99. Department of Labor, Licensing and Regulation – State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  State Board of Medical Examiners of South Carolina. *Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted: February, 1999.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- CRIMES AND OFFENSES
  Title 16. Crimes and Offenses; Chapter 3. Offenses Against the Person; Article 11. Miscellaneous Offenses

- STANDARDS FOR LICENSING HOSPICES
  Code of Regulations; Chapter 61. Department of Health and Environmental Control

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					●
Medical Practice Act		●						
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Crimes and Offenses								●
Standards for Licensing Hospices								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act				●				●
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances				●				
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Crimes and Offenses[1]								
Standards for Licensing Hospices[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

SOUTH CAROLINA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

S.C. Code Ann. § 44-53-110

§ 44-53-110. Definitions.

As used in this article and *Sections 44-49-10*, *44-49-40*, and *44-49-50*:

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"Practitioner" means:

(1) A physician, dentist, veterinarian, podiatrist, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this State.

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(+) *CRITERION 3:*
Opioids are part of professional practice

S.C. Code Ann. § 44-53-360

§ 44-53-360. Prescriptions.

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(e) Prescriptions for controlled substances in Schedule II with the exception of transdermal patches, must not exceed a thirty-one day supply. Prescriptions for Schedule II substances must be dispensed within ninety days of the date of issue, after which time they are void.

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(-) *CRITERION 12:*
Medical decisions are restricted

***CATEGORY C*:**
Restrictions regarding quantity prescribed or dispensed

(h) A prescription, in order to be effective in legalizing the possession of a controlled substance and eliminating the need for registration of the recipient, must be issued for legitimate medical purposes. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding liability rests with the pharmacist who fills and ultimately dispenses the prescription. An order purporting to be a prescription issued to a drug dependent person, not in the course of generally accepted medical treatment, but for the purpose of providing the user with controlled substances sufficient to maintain his dependence upon the substance, or to provide him with quantities of controlled substances in great excess of normal dosage ranges as recommended by the manufacturer of the substance, is not a prescription within the meaning and intent of this article; and the person filling or dispensing such an order, as well as the person issuing it, shall be deemed in violation of this section.

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(-) *CRITERION 16:*
Provisions that are ambiguous

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: "Great excess" implies there is a limit, but the limit is not specified. Also, what if a drug dependent person has pain requiring large amounts of opioid analgesics?

S.C. Code Ann. § 44-53-1620

§ 44-53-1620. Purpose.

This article is intended to improve the state's ability to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

S.C. Code Ann. § 40-47-20

§ 40-47-20. Definitions.

In addition to the definitions provided in *Section 40-1-20*, as used in this chapter unless the context indicates otherwise:

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(36) "Practice of Medicine" means:

(a) advertising, holding out to the public or representing in any manner that one is authorized to practice medicine in this State;

(b) offering or undertaking to prescribe, order, give, or administer any drug or medicine for the use of any other person;

(+) *CRITERION 2:*
Pain management is part of medical practice

(c) offering or undertaking to prevent or to diagnose, correct or treat in any manner, or by any means, methods, or devices, disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of a person, including the management or pregnancy and parturition;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

S.C. Code Regs. 61-4, Pt. 1

PART 1 Definitions, Information, Payment of Fees, Certain Exemptions, Separate Registrations, Out-of-State Dispensing of Prescriptions

101. Definitions.

As used in this regulation, the following terms shall have the meaning specified:

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(k) Individual practitioner. A physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States or the State of South Carolina, or by other jurisdiction, or otherwise permitted by the United States or the State of South Carolina, or by any other jurisdiction in which he practices to dispense a controlled substance in the regular course of professional practice, but does not include a pharmacist, a pharmacy, or any institutional practitioner;

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(+) *CRITERION 3:*
Opioids are part of professional practice

S.C. Code Regs. 61-4, Pt. 5

PART 5 Prescriptions

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508.1. Limitations on prescriptions for schedule II substances.

Prescriptions for schedule II controlled substances shall not be issued for more than a thirty-one day supply of the substance. No prescription for schedule II controlled substances shall be dispensed later than sixty days from the date of issue.

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(-) *CRITERION 12:*
Medical decisions are restricted

***CATEGORY C*:**
Restrictions regarding quantity prescribed or dispensed

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Section I: Preamble

The State Board of Medical Examiners of S.C. recognizes that principles of quality medical practice dictate that the people of the State of South Carolina have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as to reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the U.S. Agency for Health Care and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain should be based upon current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The Board of Medical Examiners is obligated under the laws of the State of South Carolina to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose. The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning - and recognizing that some types of pain cannot be completely relieved.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

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The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

Section II: Guidelines. These are guidelines, not absolutes.

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control: Nothing in this statement should be construed as advocating the imprudent use of controlled substances.

1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities including (1) urine/serum medication levels screening when requested (2) number and frequency of all prescription refills and (3) reasons for which drug therapy may be discontinued (i.e. violation of agreement).

4. Periodic Review

At reasonable intervals based upon the individual circumstance of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, such as ability to work, need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should re-evaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

5. Consultation

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

6. Medical Records

The physician should keep accurate and complete records to include (1) the medical history and physical examination (2) diagnostic, therapeutic and laboratory results (3) evaluations and consultations (4) treatment objectives (5) discussion of risks and benefits (6) treatments (7) medications [including date, type, dosage, and quantity prescribed] (8) instructions and agreements and (9) periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance with Controlled Substances Laws and Regulations

To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state, and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute pain: Acute pain is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time limited and is responsive to opioid therapy, among other therapies.

Addiction: Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as “drug dependence” and “psychological dependence.” Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Analgesic Tolerance: Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain: A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain: an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence: Physical dependence on a controlled substance is a physiologic state of neuroadaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

Pseudoaddiction: Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse: Substance abuse is the use of any substance(s) for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.

Tolerance: Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Crimes and Offenses

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

S.C. Code Ann. § 16-3-1090

§ 16-3-1090. Assisted suicide; penalties; injunctive relief.

(A) As used in this section:

(1) "Licensed health care professional" means a duly licensed physician, surgeon, podiatrist, osteopath, osteopathic physician, osteopathic surgeon, physician assistant, nurse, dentist, or pharmacist.

(2) "Suicide" means the act or instance of taking one's life voluntarily and intentionally.

(B) It is unlawful for a person to assist another person in committing suicide. A person assists another person in committing suicide if the person:

(1) by force or duress intentionally causes the other person to commit or attempt to commit suicide; or

(2) has knowledge that the other person intends to commit or attempt to commit suicide and intentionally:

(a) provides the physical means by which the other person commits or attempts to commit suicide; or

(b) participates in a physical act by which the other person commits or attempts to commit suicide.

(C) None of the following may be construed to violate subsection (B):

(1) the withholding or withdrawing of a life sustaining procedure or compliance with any other state or federal law authorizing withdrawal or refusal of medical treatments or procedures;

(2) the administering, prescribing, or dispensing of medications or procedures, by or at the direction of a licensed health care professional, for the purpose of alleviating another person's pain or discomfort, even if the medication or procedure may increase the risk of death, as long as the medication or procedure is not also intentionally administered, prescribed, or dispensed for the purpose of causing death, or the purpose of assisting in causing death, for any reason;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Standards for Licensing Hospices

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (patient physical assessment) for hospices to ensure that pain management is an essential part of patient care.

S.C. Code Regs. 61-78

61-78. Standards for Licensing Hospices.

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SECTION 1100--PATIENT PHYSICAL ASSESSMENT

1101. General (I)

A. A medical history and physical assessment shall be completed for patients within 30 days prior to or no later than 48 hours after admission. The physical assessment shall address the appropriateness of admission, medications required and self-administration status, and identification of special conditions/care required, e.g., communicable disease, such as tuberculosis, Alzheimer's disease and/or related dementia, pain management, imminent death, etc.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

SD

SOUTH DAKOTA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 34. Public Health and Safety
  Chapter 34-20. Poisons
  Chapter 34-20B. Drugs and Substances Control

- MEDICAL PRACTICE ACT
  Title 36. Professions and Occupations; Chapter 36-4. Physicians and Surgeons

- PHARMACY PRACTICE ACT
  Title 36. Professions and Occupations; Chapter 36-11. Pharmacies and Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 44. Department of Health; Article 58. Drug Control

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 20. Department of Commerce and Regulation; Division of Professional and Occupational Licensing; Article 47. Physicians and Surgeons

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 20. Department of Commerce and Regulation; Division of Professional and Occupational Licensing; Article 51. Pharmacists

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  South Dakota State Board of Medical and Osteopathic Examiners. *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: May, 2004.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HOMICIDE AND SUICIDE
  Title 22. Crimes; Chapter 22-16. Homicide and Suicide

- QUALITY OF LIFE
  Title 44. Department of Health; Article 4. Medical Facilities; Chapter 17. Residents' Rights in Nursing Facilities and Assisted Living Centers

SD

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act[1]								
Pharmacy Practice Act			●					
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Homicide and Suicide								●
Quality of Life								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act								●
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Homicide and Suicide[1]								
Quality of Life[1]								

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SOUTH DAKOTA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

S.D. Codified Laws § 34-20B-1

§ 34-20B-1. Definitions -- Generally
Terms as used in this chapter mean:

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(18) "Practitioner," a doctor of medicine, osteopathy, podiatry, optometry, dentistry, or veterinary medicine licensed to practice their profession, or pharmacists licensed to practice their profession; physician assistants certified to practice their profession; nurse practitioners and nurse midwives licensed to practice their profession; government employees acting within the scope of their employment; and persons permitted by certificates issued by the department to distribute, dispense, conduct research with respect to, or administer a substance controlled by this chapter;

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(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

S.D. Codified Laws § 36-4-30

§ 36-4-30.

The term, unprofessional or dishonorable conduct, as used in this chapter includes:

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(9) Prescribing intoxicants, narcotics, barbiturates, or other habit-forming drugs to any person in quantities and under circumstances making it apparent to the board that the prescription was not made for legitimate medicinal purposes or prescribing in a manner or in amounts calculated in the opinion of the board to endanger the well-being of an individual patient or the public in general;

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: How are the amounts calculated and how is "well-being" defined? What are the criteria for endangerment?

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

S.D. Codified Laws § 36-11-2

§ 36-11-2.
Terms used in this chapter mean:

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(21) "Practitioner," an individual licensed, registered or otherwise authorized by the jurisdiction in which he is practicing to prescribe drugs in the course of professional practice;

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(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

ARSD 44:58:01:01

44:58:01:01. Definitions

Words defined in SDCL 34-20B-1 have the same meaning when used in this article. In addition, terms used in this article mean:

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(7) "Individual practitioner," a physician, dentist, veterinarian, optometrist, nurse practitioner, nurse midwife, physician's assistant, or podiatrist licensed by the state of South Dakota or the United States to practice, who is registered or exempt from registration with the division to dispense, administer, or prescribe controlled substances in the course of practice;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

SOUTH DAKOTA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MODEL POLICY FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Section I: Preamble

The South Dakota State Board of Medical and Osteopathic Examiners recognizes that principles of quality medical practice dictate that the people of the State of South Dakota have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management. Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations just as diligently as it would allegations of other misconduct relating to prescribing practices, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The South Dakota State Board of Medical and Osteopathic Examiners is obligated under the laws of the State of South Dakota to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Physicians should not fear disciplinary action from the Board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. If such prescribing meets these criteria, the Board will support physicians whose use of controlled substances has been questioned by another regulatory or enforcement agency. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for not adhering strictly to this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

1. Evaluation of the Patient
A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan
The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment
The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. Periodic Review
The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

5. Consultation
The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records
The physician should keep accurate and complete records to include

- the medical history and physical examination;
- diagnostic, therapeutic and laboratory results;
- evaluations and consultations;
- treatment objectives;
- discussion of risks and benefits;
- informed consent;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- periodic reviews.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations
To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction
Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain
Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence
Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction
The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

SOUTH DAKOTA

STATUTES

Homicide and Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

S.D. Codified Laws § 34-12D-23

§ 34-12D-23. Administration of pain medication by health care professional -- Withdrawal of life-sustaining procedure

Any licensed health care professional who administers, prescribes, or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, does not violate § 22-16-37 unless the medications or procedures are knowingly administered, prescribed, or dispensed with a purpose to cause death. Any licensed health care professional who withholds or withdraws a life-sustaining procedure, in compliance with chapter 34-12D or in accordance with reasonable medical practice, does not violate § 22-16-37.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

REGULATIONS

Quality of Life

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

ARSD 44:04:17:09

44:04:17:09. Quality of life

A facility must provide care and an environment that contributes to the resident's quality of life, including:

(1) A safe, clean, comfortable, and homelike environment;

(2) Maintenance or enhancement of the resident's ability to preserve individuality, exercise self-determination, and control everyday physical needs;

(3) Freedom from physical or chemical restraints imposed for purposes of discipline or convenience;

(4) Freedom from verbal, sexual, physical, and mental abuse and from involuntary seclusion, neglect, or exploitation imposed by anyone, and theft of personal property;

(5) Retention and use of personal possessions, including furnishings and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents; and

(6) Support and coordination to assure pain is recognized and addressed appropriately.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for nursing facilities to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

TN

TENNESSEE

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT (*No provisions found*)
  Title 53. Food, Drugs, and Cosmetics; Chapter 11. Narcotic Drugs and Drug Control

- MEDICAL PRACTICE ACT
  Title 63. Professions and the Healing Arts; Chapter 6.Medicine and Surgery

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Title 63. Professions and the Healing Arts; Chapter 6.Medicine and Surgery;
  Part 11. Intractable Pain Treatment

- OSTEOPATHIC PRACTICE ACT
  Title 63. Professions and the Healing Arts; Chapter 9. Osteopathic Physicians

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 63. Professions and the Healing Arts; Chapter 10. Pharmacy

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Rules of the Tennessee Department of Mental Health and Developmental Disabilities; Alcohol and Drug Abuse Services Division; Chapter 0940-6-1. Controlled Substances

- MEDICAL BOARD REGULATIONS
  Rules of the Tennessee State Board of Medical Examiners; Division of Health Related Boards

- OSTEOPATHIC BOARD REGULATIONS
  Rules of the Tennessee State Board of Osteopathic Examination

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Rules of the Tennessee Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  Tennessee State Boards of Medical Examiners. *Management of Prescribing with Emphasis on Addictive or Dependence-Producing Drugs*. Approved: September 19, 1995.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- CRIMINAL OFFENSES
  Title 39. Criminal Offenses; Chapter 13. Offenses Against Person; Part 2. Criminal Homicide

- PROFESSIONAL PRACTICE
  Title 63. Professions and the Healing Arts; Chapter 1. Division of Health Related Boards

- STANDARDS FOR HOSPITALS
  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-1. Standards for Hospitals

- STANDARDS FOR NURSING HOMES
  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-6. Standards for Nursing Homes

- STANDARDS FOR RESIDENTIAL HOSPICES
  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-15. Standards for Residential Hospices

- STANDARDS FOR HOME CARE ORGANIZATIONS PROVIDING HOME HEALTH SERVICES
  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-26. Standards for Home Care Organizations Providing Home Health Services

- STANDARDS FOR HOME CARE ORGANIZATIONS PROVIDING HOSPICE SERVICES
  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-27. Standards for Home Care Organizations Providing Hospice Services

- STANDARDS FOR HIV SUPPORTIVE LIVING FACILITIES
  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-28. Standards for HIV Supportive Living Facilities

- STANDARDS FOR HOME CARE ORGANIZATIONS PROVIDING PROFESSIONAL SUPPORT SERVICES
  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-34. Standards for Home Care Organizations Providing Professional Support Services

- STANDARDS FOR OUTPATIENT DIAGNOSTIC CENTERS
  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-35. Standards for Outpatient Diagnostic Centers

TN

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Intractable Pain Treatment Act		●	●	●	●			●
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances[1]								
Medical Board		●	●		●	●		●
Osteopathic Board		●	●	●	●	●	●	●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement						●		
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Criminal Offenses			●					●
Professional Practice		●						
Standards/Hospitals								●
Standards/Nursing Homes								●
Standards/Residential Hospices								●
Standards/Home Care Orgs - Hospice Services								●
Standards/Home Care Orgs. -Home Health Services								●
Standards/HIV Supportive Living Facilities								●
Standards/Home Care Orgs. – Prof. Support Services								●
Standards/Outpt Diagnostic Ctrs								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act				●				●
Intractable Pain Treatment Act		●	●					●
Osteopathic Practice Act				●				
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances[1]								
Medical Board		●						●
Osteopathic Board								●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement	●		●	●				
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Criminal Offenses[1]								
Professional Practice[1]								
Standards/Hospitals[1]								
Standards/Nursing Homes[1]								
Standards/Residential Hospices[1]								
Standards/Home Care Orgs - Hospice Services[1]								
Standards/Home Care Orgs. -Home Health Services[1]								
Standards/HIV Supportive Living Facilities[1]								
Standards/Home Care Orgs. – Prof. Support Services[1]								
Standards/Outpt Diagnostic Ctrs[1]								

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Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tenn. Code Ann. § 63-6-214

63-6-214. Grounds for license denial, suspension or revocation -- Reporting misconduct

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(b) The grounds upon which the board shall exercise such power include, but are not limited to:

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(12) Dispensing, prescribing or otherwise distributing any controlled substance or any other drug not in the course of professional practice, or not in good faith to relieve pain and suffering, or not to cure an ailment, physical infirmity or disease, or in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition;

(13) Dispensing, prescribing or otherwise distributing to any person a controlled substance or other drug if such person is addicted to the habit of using controlled substances without making a bona fide effort to cure the habit of such patient;

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Implies that there is a limit on the amount of controlled substances that can be prescribed or dispensed, but that limit is not specified.

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

COMMENT: Tennessee law does not seem to create an exemption for patients with pain and a history of addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tenn. Code Ann. § 63-6-1101 -- 1109

63-6-1101. Short title

This part may be known and cited as the "Intractable Pain Treatment Act."

63-6-1102. Definitions

For the purposes of this part:

(1) "Board" means the board of medical examiners.
(2) "Chemical dependency" means:

(A) The abuse of alcohol or a controlled substance;
(B) A pathological use of alcohol or a controlled substance that chronically impairs the applicant's ability to competently provide legal advice or services; or
(C) A physiological or physical dependence on alcohol or a controlled substance.

(3) "Intractable pain" means a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts.
(4) "Physician" means a physician licensee of the board of medical examiners or an osteopathic physician.

63-6-1103. Legislative declarations

The general assembly finds and declares all of the following:
(1) The state has a right and duty to control the illegal use of opiate drugs.
(2) Inadequate treatment of acute and chronic pain originating from cancer or noncancerous conditions is a significant health problem.
(3) For some patients, pain management is the single most important treatment a physician can provide.
(4) A patient suffering from severe chronic intractable pain should have access to proper treatment of such patient's pain.
(5) Due to the complexity of their problems, many patients suffering from severe chronic intractable pain may require referral to a physician with expertise in the treatment of severe chronic intractable pain. In some cases, severe chronic intractable pain is best treated by a team of clinicians in order to address the associated physical, psychological, social, and vocational issues.
(6) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute and severe chronic intractable pain can be safe.
(7) Opiates can be an accepted treatment for patients in severe chronic intractable pain who have not obtained relief from any other means of treatment.
(8) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve such patient's severe chronic intractable pain.
(9) A physician treating a patient who suffers from severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain as long as the prescribing physician is in conformance with the provisions of this part.
(10) A patient who suffers from severe chronic intractable pain has the option to choose opiate medication for the treatment of the severe chronic intractable pain as long as a physician has first determined that such treatment is appropriate and medically necessary and the prescribing is in conformance with the provisions of this part.
11) The patient's physician may refuse to prescribe opiate medication for a patient who requests the treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians whose primary practices are the treatment of severe chronic intractable pain with methods that include the use of opiates.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

(-) *CRITERION 10:*
Implies opioids are not part of professional practice

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

63-6-1104. Pain patient's bill of rights

a) This section may be known and cited as the "Pain Patient's Bill of Rights."
b) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve such patient's severe chronic intractable pain.
c) A patient who suffers from severe chronic intractable pain has the option to choose opiate medications to relieve severe chronic intractable pain without first having to submit to an invasive medical procedure, which is defined as surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device, as long as the prescribing physician acts in conformance with the provisions of this part.
d) The patient's physician may refuse to prescribe opiate medication for the patient who requests a treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates.
e) A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain, as long as that prescribing physician is in conformance with this part.
f) A patient may voluntarily request that such patient's physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification.
g) Nothing in this section shall do either of the following:
(1) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices or other provisions set forth in this chapter or the regulations adopted thereunder; or
(2) Limit the applicability of any federal statute or federal regulation or any of the other statutes or regulations of this state that regulate dangerous drugs or controlled substances.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Sections (b) and (c) recognize the patient's right to choose or refuse different types of treatments.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: It appears that the Pain Patient's Bill of Rights requires that all opiate treatment for patients with "severe chronic intractable pain," must be according to this policy, thus requiring an evaluation by a second physician in every case, and excluding certain patient populations. Also, is it legal for a physician to prescribe medically necessary dosages of opioids to patients with severe chronic pain who are not qualified under this policy?

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: How does this qualify as a "Pain Patient's Bill of Rights" ? This language falls short of providing any rights to specific treatment and may establish a false expectation for adequate pain management.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: The phrase "severe chronic intractable pain" is used throughout this policy. The intended result of such elaborate and unconventional medical terminology is unclear, but appears to limit the patient population which should be given access to "proper treatment" of pain, including the use of opioids, and which is given the option to request or reject any treatments. What is the effect of this law on patients with pain that is not severe, chronic, and intractable? Is there a greater risk of discipline for a physician who would prescribe opioids to a patient with pain which was not severe, chronic, and intractable?

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY C:
Conflicting or inconsistent policies or provisions

COMMENT: This provision may be confusing, and even in conflict, when considered in conjunction with provision §63-6-1103(7) which states that patients qualify for opiate treatment after "other means of treatment;" in §63-6-1104©, the patient does not have to "submit" to certain treatments.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

63-6-1105. Physician authorized to write prescriptions
Notwithstanding any other provision of law, a physician may prescribe or administer dangerous drugs or controlled substances to a person in the course of the physician's treatment of a person for intractable pain to provide adequate pain treatment.

63-6-1106. Disciplinary action against physicians

a) No physician may be subject to disciplinary action by the board for prescribing or administering appropriate amounts, combinations, or durations of dangerous drugs or controlled substances in the course of treatment of a person for intractable pain.
b) The board is authorized to set by rule guidelines to govern treatment under this part. Such guidelines may include requirements for documented medical history, written treatment plans, discussion of benefits and risks of the treatment, periodic review, and the keeping of appropriate records. Such guidelines may be in addition to specific requirements for persons with substance abuse issues governed by § 63-6-1107.

63-6-1107. Treatment of chemically dependent individuals
a) Notwithstanding any other provision of this part, subsections c and d shall govern the treatment of persons for chemical dependency by a physician because of their use of dangerous drugs or controlled substances.
b) The provisions of this part provide no authority to a physician to prescribe or administer dangerous drugs or controlled substances to a person for other than legitimate medical purposes as defined by the board and who the physician knows or should know to be using drugs for nontherapeutic purposes.
c) The provisions of this part authorize a physician to treat a patient who develops an acute or chronic painful medical condition with a dangerous drug or a controlled substance to relieve the patient's pain using appropriate doses, for an appropriate length of time, and for as long as the pain persists. A patient under this subsection includes a person who:
1) Is a current drug abuser;
2) Is not currently abusing drugs but has a history of drug abuse; or
3) Lives in an environment that poses a risk for drug misuse or diversion of the drug to illegitimate use.
d) A physician who treats a patient under subsection c shall monitor the patient to ensure the prescribed dangerous drug or controlled substance is used only for the treatment of the patient's painful medical condition. To ensure that the prescribed dangerous drug or controlled substance is not being diverted to another use and the appropriateness of the treatment of the patient's targeted symptoms, the physician shall:
1) Specifically document the:
A)Understanding between the physician and patient about the patient's prescribed treatment;
B) Name of the drug prescribed;
C) Dosage and method of taking the prescribed drug;
D) Number of dose units prescribed; and
E) Frequency of prescribing and dispensing the drug; and
2) Consult with a psychologist, psychiatrist, expert in the treatment of addictions, or other health care professional, as appropriate.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (rules) for the Board to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

63-6-1109. Use of physician's assistants or other personnel – Licensing – Continued education

a) Any physician who practices pain management shall also be able to hire physician assistants to assist such physician's in such physician's practice. Any of these assistants shall be a licensed physician assistant according to the requirements in § 63-19-105(a) except for any person who meets the following requirements;

(1) Is sixty-five (65) years of age or older;
(2) Was granted a degree in pre-medical studies in 1960;
(3) Was granted a master of science degree from the University of Tennessee in 1991;
(4) Was an instructor and assistant professor during the time period 1977-97 at East Tennessee State University in Surgical Technology;
(5) Was an instructor in surgical techniques and instruments to medical students and surgical residents at the Quillen College of Medicine at East Tennessee State University;
(6) Met the standards and qualifications of the American Association of Physician Assistants in March of 1976 and was rated as "physicians assistant – SP-2";
(7) Satisfactorily completed the postgraduate course "clinical skills for physicians' assistants V" in September 1977 from the Hahnemann Medical College and Hospital in Philadelphia, Pennsylvania:
(8) Held an "assistants renewal certificate" issued by the Virginia Board of Medicine from July 1, 1977, to June 30, 1978; and
(9) Was recognized as a "certified surgical assistant" by the National Surgical Assistant Association in May of 1987.

b) Such person shall be issued a license within sixty (60) days upon submission of evidence to the board of medical examiners that such person met all of the above criteria; provided, however, that such person shall only work under the supervision of one (1) physician who is in the sole practice of pain management and rehabilitation medicine. Such person's duties shall only include helping the physician examine the patients in the physician's office, doing diagnostic EMGs, ordering appropriate lab x-rays studies, seeing the physician's hospital patients on hospital rounds and writing orders to be countersigned by such physician, but, at no time shall this person be allowed to prescribe medicine. Such person shall also have the ability to work under a physician, who is in the sole practice of pain management and rehabilitation medicine, while performing extensive medical missionary trips in underpriviledged countries. Any continuing education requirements for a person meeting the above criteria shall not be waived.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Osteopathic Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tenn. Code Ann. § 63-9-111

63-9-111. Denial, suspension and revocation of licenses or certificates -- Enjoining violations -- Enforcement –Investigations

(a) The board has the power to:

(1) Deny an application for a license to any applicant who applies for the same through reciprocity or otherwise;

(2) Permanently or temporarily withhold issuance of a license;

(3) Suspend or limit or restrict a previously issued license for such time and in such manner as the board may determine;

(4) Reprimand or take such action in relation to disciplining an applicant or licensee as the board in its discretion may deem proper; or

(5) Permanently revoke a license.

(b) The grounds upon which the board shall exercise the powers set forth in subsection (a) include, but are not limited to:

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(12) Dispensing, prescribing or otherwise distributing to any person a controlled substance or other drug if such person is addicted to the habit of using controlled substances without making a bona fide effort to cure the habit of such patient;

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(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tenn. Comp. R. & Regs. R. 0880-2-.14

0880-2-.14 SCOPE OF PRACTICE

(1) Policy Statement - The scope of practice of physicians in Tennessee is broadly defined and includes many aspects which if not particularly regulated could lead to serious ramifications for the consuming public. This Rule is to designate specific areas in the practice of medicine for regulation the violation of which may result in disciplinary action pursuant to either T.C.A. §§ 63-6-214(b)(1) or 63-6-214(b)(4) or 63-6-214(b)(12).

(2) Pharmaceutical Dispensing - Physicians who elect to dispense medication for remuneration must comply with the following:

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(d) Dispensing or prescribing controlled substances in amounts or for durations not medically necessary, advisable or justified is considered to be practicing beyond the scope of the professional practice.

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(6) Authority of Physician to Prescribe for the Treatment of Pain - Purpose - The purpose of this chapter is to recognize that some dangerous drugs and controlled substances are indispensable for the treatment of pain, and are useful for relieving and controlling many other related symptoms that patients may suffer. It is the position of the board that these drugs may be prescribed for the treatment of pain and other related symptoms after a reasonably based medical diagnosis has been made, in adequate doses, and for appropriate lengths of time, which in some cases may be as long as the pain or related symptoms persist. The board recognizes that pain, including intractable pain, and many other related symptoms are subjective complaints and that the appropriateness and the adequacy of drug and dose will vary from individual to individual. The practitioner is expected to exercise sound medical judgment in treating pain and related symptoms with dangerous drugs and controlled substances.

(a) Definitions. The following words and terms, as used in this rule shall have the following meanings in the context of providing medications for pain and related symptoms.

1. Abuser of narcotic drugs, controlled substances and dangerous drugs - A person who takes a drug or drugs for other than legitimate medical purposes.

2. Intractable pain - A pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts.

3. Non-therapeutic in nature or manner - A medical use or purpose that is not legitimate.

4. Prescribing pharmaceuticals or practicing consistent with the public health and welfare - Prescribing pharmaceuticals and practicing medicine for a legitimate medical purpose in the usual course of professional practice.

(b) No physician is required to provide treatment to patients with intractable pain with opiate medications but when refusing to do so shall inform the patient that there are physicians whose primary practice is in the treatment of severe, chronic, intractable pain with methods including the use of opiates. If the patient requests a referral to such a physician, and the physician makes such a referral that referral shall be noted in the patient's medical records.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: "Amounts or durations not medically necessary, advisable, or justified" implies there is a known standard, but the standard is not specified.

(-) *CRITERION 10:*
Implies opioids are not part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

(c) If a physician provides medical care for persons with intractable pain, with or without the use of opiate medications, to the extent that those patients become the focus of the physician's practice the physician must be prepared to document specialized medical education in pain management sufficient to bring the physician within the current standard of care in that field which shall include education on the causes, different and recommended modalities for treatment, chemical dependency and the psycho/social aspects of severe, chronic intractable pain.

(d) The treatment of persons with an acute or chronic painful medical condition who also require treatment for chemical dependency by a physician shall be governed by T.C.A. § 63-6-1107 (c) and (d).

(e) Guidelines - The Tennessee Board of Medical Examiners will use the following guidelines to determine whether a physician's conduct violates T.C.A. § 63-6-214 (b) (12) through (14) in regard to the prescribing, administering, ordering, or dispensing of pain medications and other drugs necessary to address their side effects.

(+) *CRITERION 2:*
Pain management is part of medical practice

1. The treatment of pain, including intractable pain, with dangerous drugs and controlled substances is a legitimate medical purpose when done in the usual course of professional practice.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

2. A physician or surgeon duly authorized to practice medicine in Tennessee and to prescribe controlled substances and dangerous drugs in this state shall not be subject to disciplinary action by the board for prescribing, ordering, administering, or dispensing dangerous drugs or controlled substances for the treatment and relief of pain, including intractable pain, in the usual course of professional practice for a legitimate medical purpose in compliance with applicable state and federal law.

3. Prescribing, ordering, administering, or dispensing dangerous drugs or controlled substances for pain will be considered to be for a legitimate medical purpose if based upon accepted scientific knowledge of the treatment of pain, including intractable pain, not in contravention of applicable state or federal law, and if prescribed, ordered, administered, or dispensed in compliance with the following guidelines where appropriate and as is necessary to meet the individual needs of the patient:

(i) After a documented medical history, which may be provided orally or in writing by the patient, and physical examination by the physician providing the medication including an assessment and consideration of the pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance;

(ii) Pursuant to a written treatment plan tailored for the individual needs of the patient by which treatment progress and success can be evaluated with stated objectives such as pain relief and/or improved physical and psychosocial function. Such a written treatment plan shall consider pertinent medical history and physical examination as well as the need for further testing, consultations, referrals, or use of other treatment modalities;

(iii) The physician should discuss the risks and benefits of the use of controlled substances with the patient or guardian;

(iv) Subject to documented periodic review of the care by the physician at reasonable intervals in view of the individual circumstances of the patient in regard to progress toward reaching treatment objectives which takes into consideration the course of medications prescribed, ordered, administered, or dispensed as well as any new information about the etiology of the pain;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

[CONTINUED]

(v) Complete and accurate records of the care provided as set forth in parts (i)-(iv) of this paragraph should be kept. When controlled substances are prescribed, names, quantities prescribed, dosages, and number of authorized refills of the drugs should be recorded, keeping in mind that pain patients with a history of substance abuse or who live in an environment posing a risk for medication misuse or diversion require special consideration. Management of these patients may require closer monitoring by the physician managing the pain and consultation with appropriate health care professionals.

4. A decision by a physician not to strictly adhere to the provisions of paragraph 3 of this section will, for good cause shown, be grounds for the board to take no disciplinary action in regard to the physician. Each case of prescribing for pain will be evaluated on an individual basis. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

5. If the provisions as set out in subparagraphs (1)-(4) of this section are met, and if all drug treatment is properly documented, the board will consider such practices as prescribing in a therapeutic manner, and prescribing and practicing medicine in a manner consistent with public health and welfare.

6. Quantity of pharmaceutical and chronicity of prescribing will be evaluated on the basis of the documented appropriate diagnosis and treatment of the recognized medical indication, documented persistence of the recognized medical indication, and properly documented follow-up evaluation with appropriate continuing care as set out in this rule.

7. A physician may use any number of treatment modalities for the treatment of pain, including intractable pain, which are consistent with legitimate medical purposes.

8. These rules shall not be construed so as to apply to the treatment of acute pain with dangerous drugs or controlled substances for purposes of short-term care.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Osteopathic Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tenn. Comp. R. & Regs. R. 1050-2-.13

1050-2-.13 SPECIFICALLY REGULATED AREAS AND ASPECTS OF MEDICAL PRACTICE

(1) The scope of practice of osteopathic physicians in Tennessee is broadly defined in the Osteopathic Medical Act and promulgated rules and includes many aspects which if not particularly regulated could lead to serious ramifications for the consuming public. This rule is to designate specific areas in the practice of osteopathic medicine for regulation the violation of which may result in disciplinary action pursuant to T.C.A. § 63-9-111.

(2) Pharmaceutical Dispensing - Osteopathic physicians who elect to dispense medication for remuneration must comply with the following:

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(d) Dispensing or prescribing controlled substances in amounts or for durations not medically necessary, advisable or justified is considered to be practicing beyond the scope of the professional practice.

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5) Guidelines for the Use of Controlled Substances for the Treatment of Pain --

(a) Purposes and Intent

1. The Board recognizes that principles of quality medical practice dictate that the people of the State of Tennessee have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

2. Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed pursuant to the Tennessee Intractable Pain Treatment Act to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

3. The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the U.S. Agency for Health Care and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

4. The Board is obligated under the laws of the State of Tennessee to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

[CONITINUED ON NEXT PAGE]

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: "Amounts or durations not medically necessary, advisable, or justified" implies there is a known standard, but the standard is not specified.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Osteopathic Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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5. Physicians should not fear disciplinary action from the Board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state and federal law.

6. Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs-including any improvement in functioning-and recognizing that some types of pain cannot be completely relieved.

7. The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(b) Guidelines - The Board adopts the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient - A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan - The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment - The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible.

4. Periodic Review - At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

[CONITINUED ON NEXT PAGE]

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Osteopathic Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

5. Consultation - The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. The management of pain in patients with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records - The physician should keep accurate and complete records to include the medical history and physical examination; diagnostic, therapeutic and laboratory results; evaluations and consultations; treatment objectives; discussion of risks and benefits; treatments; medications (including date, type, dosage and quantity prescribed); instructions and agreements; and periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review.

(c) No physician is required to provide treatment to patients with intractable pain with opiate medications but when refusing to do so shall inform the patient that there are physicians whose primary practice is in the treatment of severe, chronic, intractable pain with methods including the use of opiates. If the patient requests a referral to such a physician, and the physician makes such a referral that referral shall be noted in the patient's medical records.

(d) If a physician provides medical care for persons with intractable pain, with or without the use of opiate medications, to the extent that those patients become the focus of the physician's practice the physician must be prepared to document specialized medical education in pain management sufficient to bring the physician within the current standard of care in that field which shall include education on the causes, different and recommended modalities for treatment, chemical dependency and the psycho/social aspects of severe, chronic intractable pain.

(e) The treatment of persons with an acute or chronic painful medical condition who also require treatment for chemical dependency by a physician shall be governed by subsections T.C.A. § 63-6-1107 (c) and (d).

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MANAGEMENT OF PRESCRIBING WITH EMPHASIS ON
ADDICTIVE OR DEPENDENCE-PRODUCING DRUGS

The Tennessee Board of Medical Examiners is charged by the General Assembly to protect the citizens of the State from harmful physician management. A significant number of physicians who are asked to appear before the Board are required to do so because of their lack of information about the management and responsibilities involved in prescribing controlled substances. Frequently, the inadvertent offender is a physician with a warm heart and a desire to relieve pain and misery, who is always pressed for time and finds himself or herself prescribing controlled drugs on demand over prolonged periods without adequate documentation. These are often for chronic ailments such as headache, arthritis, old injuries, chronic orthopedic problems, backache and anxiety. (Terminal cancer pain management is not a consideration here.) The purpose of the Board of Medical Examiners in presenting the following information is to help licensed physicians in Tennessee consider and reevaluate their prescribing practice of controlled substances. Practicing physicians have often mentioned the abrupt education they received in their own prescribing patterns. Moreover, there have been many request to the Board from physicians requesting detailed information on prescribing in certain specific situations.

It is not what you prescribe, but how well you manage the patient's care, and document that care in legible form, that is important.

The prescribing matters that come before the Board are almost always related to the prescription of controlled substances. We feel that a majority of instances where physicians have been disciplined by the Board for prescribing practices could have been avoided completely if they had followed the steps that are being outlined here.

To prevent any misunderstanding, it is necessary to state what the Board **does not** have.

It **does not** have a list of "bad" or "disallowed" drugs, except in certain circumstances, amphetamines, amphetamine-like substances and central nervous system stimulants. (See, Board of Medical Examiner Rule 0880-2-.14, a copy of which is available to you by contacting the Board's administrative office at (615) 367-6231.) All formulary drugs, except as previously noted, are good if prescribed and administered when properly indicated. Conversely, all drugs are ineffective, dangerous, or even lethal when used inappropriately.

(+) *CRITERION 6: Prescription amount alone does not determine legitimacy*

It **does not** have some magic formula for determining the dosage and duration of administration for any drug. These are aspects of prescribing that must be determined within the confines of the individual clinical case, and continued under proper monitoring. What is good for one patient may be insufficient or fatal for another.

What the Board **does** have is the expectation that physicians will create a record that shows:
- Proper indication for the use of drug or other therapy;
- Monitoring of the patient where necessary;
- The patient's response to therapy based on follow-up visits; and
- All rationale for continuing or modifying the therapy.

[CONTINUED ON NEXT PAGE]

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

STEP ONE
First and foremost, before you prescribe anything, start with a diagnosis which is supported by history and physical findings, and by the results of any appropriate tests. Too many times a doctor is asked why he or she prescribed a particular drug, and the response is, "Because the patient has arthritis." Then the doctor is asked, "How did you determine that?" and the answer is, "Because that's what the patient complained of." Nothing in the record or in the doctor's recollection supports the diagnosis except the patient's assertion. **Do a workup sufficient to support a diagnosis** including all necessary tests.

STEP TWO
Create a treatment plan which includes the use of appropriate non-addictive modalities, and make referrals to appropriate specialists, such as neurologists, orthopedists, psychiatrists, etc. The result of the referral should be included in the patient's chart.

STEP THREE
Before beginning a regimen of controlled drugs, make a determination through trial or through a documented history that **non-addictive modalities are not appropriate or they do not work.** A finding of intolerance or allergy to NSAIDs is one thing, but the assertion of the patient that, "Gosh, Doc, nothing seems to work like that Percodan stuff!" is quite another. Too many of the doctors the Board has seen have started a treatment program with powerful controlled substances without ever considering other forms of treatment.

(-) *CRITERION 9:*
Opioids are a last resort

STEP FOUR
Make sure you are not dealing with a drug-seeking patient. If you know the patient, review the prescription records in the patient's chart and discuss the patient's chemical history before prescribing a controlled drug. If the patient is new or otherwise unknown to you, at a minimum obtain an oral drug history, and discuss chemical use and family chemical history with the patient.

STEP FIVE
It is a good idea to obtain the informed consent of the patient before using a drug that has the potential to cause dependency problems. **Take the time to explain the relative risks and benefits of the drug and record in the chart the fact that this was done.** When embarking on what appears to be the long term use of a potentially addictive substance, it may be wise to hold a family conference and explain the relative risks of dependency or addiction and what that may mean to the patient and to the patient's family. Refusal of the patient to permit a family conference may be significant information.

STEP SIX
Maintain regular monitoring of the patient, including frequent physical monitoring. If the regimen is for a prolonged drug use, it is very important to monitor the patient for the root condition which necessitates the drug **and** for the side effects of the drug itself. This is true no matter what type of controlled substance is used or what schedule it belongs to. Also, remember that with certain conditions, drug holidays are appropriate. This allows you to check to see whether the original symptoms recur when the drug is not given - indicating a continuing legitimate need for the drug or whether withdrawal symptoms occur - indicating dependence.

(-) *CRITERION 12:*
Medical decisions are restricted

***CATEGORY D*:**
Undue prescription limitations

COMMENT: "Drug holidays" are no longer recognized as appropriate medical practice.

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

[CONTINUED ON NEXT PAGE]

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

STEP SEVEN

Make sure YOU are in control of the supply of the drug. To do this, at a minimum you must keep detailed records of the type, dose, and amount of the drug prescribed. You must also monitor, record and personally control all refills. Do not authorize your office personnel to refill prescriptions without consulting you. **One good way to accomplish this is to require the patient to return to obtain refill authorization, at least part of the time.** Records of the cumulative dosage and average daily dosage are especially valuable. A thumbnail sketch of three hypothetical cases will illustrate our point here. In the first case, a physician prescribes Tussionex to a patient for approximately five years for a cumulative dosage of nineteen and one half gallons. In the second case, a physician prescribes, Tylenol 3's to a patient for slightly more than a year at the average daily rate of 30 per day! The third case is very similar, except that it was Tylenol 4's at the rate of 20 per day. Some quick observations:

- No physician who was aware of that kind of prescribing would have continued with it.
- Few, if any, patients could have been consuming that much Tylenol with codeine. In all likelihood, they were reselling it.

Another important part of controlling the supply of drugs is to check on whether the patient is obtaining drugs from other physicians. Checking with pharmacies and pharmacy chains and other health care providers may tell you whether a patient is obtaining extra drugs or the patient is doctor shopping. If you are aware it is occurring, contact other physicians and health professionals in your area.

STEP EIGHT

Maintaining regular contact with the patient's family is a valuable source of information on the patient's response to the therapy regimen, and may be much more accurate and objective than feedback from the patient alone.

The family is a much better source of information on behavioral changes, especially dysfunctional behavior, than is the patient. Dysfunctional changes may be observable when the patient is taking the drug, or when the drug is withdrawn. These changes, at either time, may be a symptom of dependency or addiction.

The family is also a good source of information on whether the patient is obtaining drugs from other sources, or is self-medicating with other drugs or alcohol.

STEP NINE

To reiterate, one of the most frequent problems faced by a physician when he or she comes before the Board or other outside review bodies is **inadequate records**. It is entirely possible that the doctor did everything correctly in managing a case, but without records which reflect all the steps that went into the process, the job of demonstrating it to any outside reviewer becomes many times more difficult. Luckily, this is a problem which is solvable.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

TENNESSEE

STATUTES

Criminal Offenses

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tenn. Code Ann. § 39-13-216

39-13-216. Assisted suicide

(a) The board has the power to:

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(b) It is not an offense under this section to:

(1) Withhold or withdraw medical care as defined by *§ 32-11-103*;

(2) Prescribe, dispense, or administer medications or perform medical procedures calculated or intended to relieve another person's pain or discomfort (but not calculated or intended to cause death), even if the medications or medical procedures may hasten or increase the risk of death;

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Tenn. Code Ann. § 39-17-402

39-17-402. Definitions.

As used in this part and title 53, chapter 11, parts 3 and 4, unless the context otherwise requires:

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(23) "Practitioner" means:

(A) A physician, dentist, optometrist, veterinarian, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessens its impact on patient treatment, and the practitioners who provide it.

(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Professional Practice

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tenn. Code Ann. § 63-1-102

63-1-102. Chapter definitions

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(2) "Practice of the healing arts" means offering or undertaking to diagnose, treat, operate on, or prescribe for any human pain, injury, disease, deformity, or physical or mental condition. The practice of acupuncture is hereby declared to be included within the definition of "practice of the healing arts" as defined by this section; and

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(+) *CRITERION 2:*
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Standards for Hospitals

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospitals to ensure that pain management is an essential part of patient care.

Tenn. Comp. R. & Regs. R. 1200-8-1-.04

1200-8-1-.04 ADMINISTRATION

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(8) The hospital shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

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Tenn. Comp. R. & Regs. R. 1200-8-1-.12

1200-8-1-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

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(g) To have appropriate assessment and management of pain;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Standards for Nursing Homes

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tenn. Comp. R. & Regs. R. 1200-8-6

1200-8-6-.04 ADMINISTRATION

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(18) The nursing home shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

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1200-8-6-.12 RESIDENT RIGHTS.

(1) The nursing home shall establish and implement written policies and procedures setting forth the rights of residents for the protection and preservation of dignity, individuality and, to the extent medically feasible, independence. Residents and their families or other representatives shall be fully informed and documentation shall be maintained in the resident's file of the following rights:

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(x) To have appropriate assessment and management of pain;

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.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for nursing homes to ensure that pain management is an essential part of patient care.

REGULATIONS

Standards for Residential Hospices

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tenn. Comp. R. & Regs. R. 1200-8-15

1200-8-15-.04 ADMINISTRATION

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(4) The residential hospice shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

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1200-8-15-.12 PATIENT/RESIDENT RIGHTS.

(1) The residential hospice shall establish and implement written policies and procedures setting forth the rights of patients and residents for the protection and preservation of dignity and individuality. Each patient and resident has at least the following rights:

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(m) To have appropriate assessment and management of pain;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for residential hospices to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Standards for Home Care Organizations Providing Home Health Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for home care organizations providing home health services to ensure that pain management is an essential part of patient care.

Tenn. Comp. R. & Regs. R. 1200-8-26-.04

1200-8-26-.04 ADMINISTRATION

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(3) The home health agency shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

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Tenn. Comp. R. & Regs. R. 1200-8-26-.12

1200-8-26-.12 PATIENT RIGHTS

(1) Each patient has at least the following rights:

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(b) To have appropriate assessment and management of pain;

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REGULATIONS

Standards for Home Care Organizations Providing Hospice Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tenn. Comp. R. & Regs. R. 1200-8-27-.04

1200-8-27-.04 ADMINISTRATION

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(4) The hospice agency shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

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1200-8-27-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

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(c) To have appropriate assessment and management of pain;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for home care organizations providing hospice services to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Standards for HIV Supportive Living Facilities

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for HIV supportive living facilities to ensure that pain management is an essential part of patient care.

Tenn. Comp. R. & Regs. R. 1200-8-28-.04

1200-8-28-.04 ADMINISTRATION

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(4) The HIV supportive living facility shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

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Tenn. Comp. R. & Regs. R. 1200-8-28-.12

1200-8-28-.12 RESIDENT RIGHTS

(1) The HIV supportive living facility shall establish and implement written policies and procedures setting forth the rights of residents for the protection and preservation of dignity and individuality. Each resident has at least the following rights:

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(m) To have appropriate assessment and management of pain;

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REGULATIONS

Standards for Home Care Organizations Providing Professional Support Services

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tenn. Comp. R. & Regs. R. 1200-8-34-.12

1200-8-34-.12 CONSUMER RIGHTS

(1) Each consumer has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To have appropriate assessment and management of pain;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for home care organizations providing professional support services to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Standards for Outpatient Diagnostic Centers

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for outpatient diagnostic centers to ensure that pain management is an essential part of patient care.

Tenn. Comp. R. & Regs. R. 1200-8-35-.12

1200-8-35-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

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(f) To have appropriate assessment and management of pain;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

TX

TEXAS

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Health and Safety Code; Title 6. Food, Drugs, Alcohol, and Hazardous Substances; Subtitle C. Substance Abuse Regulation and Crimes; Chapter 481. Texas Controlled Substances Act

- INTRACTABLE PAIN TREATMENT ACT (*Part of Professional Practice Act*)
  Occupations Code; Title 3. Health Professions; Subtitle A. Provisions Applying to Health Professions Generally; Chapter 107. Intractable Pain Treatment

- MEDICAL PRACTICE ACT
  Occupations Code; Title 3. Health Professions; Subtitle B. Physicians

- PHARMACY PRACTICE ACT
  Occupations Code; Title 3. Health Professions; Subtitle J. Pharmacy and Pharmacists

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 37. Public Safety and Corrections; Part 1. Texas Department of Public Safety; Chapter 13. Controlled Substances

- MEDICAL BOARD REGULATIONS
  Title 22. Examining Boards; Part 9. Texas Medical Board

- PHARMACY BOARD REGULATIONS
  Title 22. Examining Boards; Part 15. Texas State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- PHARMACY BOARD POLICY STATEMENT
  Texas State Board of Pharmacy. *Texas State Board of Pharmacy Position Statement on the Treatment of Pain*. Adopted: August 29, 2001.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- PAIN TREATMENT EDUCATION

  Education Code; Title 3. Higher Education; Subtitle A. Higher Education in General; Chapter 51. Provisions Generally Applicable to Higher Education; Subchapter F. Required and Elective Courses

- LICENSING OF HOSPITALS

  Title 25. Health Services; Part 1. Department of State Health Services; Chapter 133. Hospital Licensing; Subchapter C. Operational Requirements

- STANDARDS FOR LICENSURE

  Title 40. Social Services and Assistance; Part 1. Department of Aging and Disability Services; Chapter 92. Licensing Standards for Assisted Living Facilities; Subchapter C. Standards for Licensure

- LICENSING OF HOME AND COMMUNITY SUPPORT SERVICES AGENCIES

  Title 40. Social Services and Assistance; Part 1. Department of Aging and Disability Services; Chapter 97. Licensing Standards for Home and Community Support Services Agencies; Subchapter D. Additional Standards Specific to License Category and Specific to Special Services

TX

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Intractable Pain Treatment Act		●	●	●	●			●
Medical Practice Act								●
Pharmacy Practice Act			●					●
REGULATIONS								
Controlled Substances			●					
Medical Board		●	●		●	●	●	●
Pharmacy Board			●					●
OTHER GOVERNMENTAL POLICIES								
Pharmacy Board Policy Statement		●	●	●	●		●	
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Pain Treatment Education								●
Licensing of Hospitals								●
Standards for Licensure								●
Licensing of Home and Community Support Services Agencies								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

TX

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act						●		
Intractable Pain Treatment Act		●				●		●
Medical Practice Act				●				
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances						●		
Medical Board[1]								
Pharmacy Board						●		●
OTHER GOVERNMENTAL POLICIES								
Pharmacy Board Policy Statement[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Pain Treatment Education[1]								
Licensing of Hospitals[1]								
Standards for Licensure[1]								
Licensing of Home and Community Support Services Agencies[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tex. Health & Safety Code § 481.002

§ 481.002. Definitions

In this chapter:

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(39) "Practitioner" means:

(+) *CRITERION 3:*
Opioids are part of professional practice

(A) a physician, dentist, veterinarian, podiatrist, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, analyze, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state;

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§ 481.075. Official Prescription Program

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(b) Each official prescription form must be sequentially numbered.

(c) The director shall issue official prescription forms to practitioners for a fee covering the actual cost of printing, processing, and mailing the forms at 100 a package. Before mailing or otherwise delivering prescription forms to a practitioner, the director shall print on each form the number of the form and any other information the director determines is necessary.

(d) A person may not obtain an official prescription form unless the person is a practitioner as defined by Section 481.002 (39) (A) or an institutional practitioner.

(e) Each official prescription form used to prescribe a Schedule II controlled substance must contain:

(1) information provided by the prescribing practitioner, including:

(A) the date the prescription is written;

(B) the controlled substance prescribed;

(C) the quantity of controlled substance prescribed, shown numerically followed by the number written as a word;

(D) the intended use of the controlled substance or the diagnosis for which it is prescribed and the instructions for use of the substance;

(E) the practitioner's name, address, and Federal Drug Enforcement Administration number; and

(F) the name, address, and date of birth or age of the person for whom the controlled substance is prescribed;

(2) information provided by the dispensing pharmacist, including the date the prescription is filled; and

(3) the signatures of the prescribing practitioner and the dispensing pharmacist.

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(-) CRITERION 14:
Undue prescription requirements

COMMENT: Federal Controlled Substances law does not require the diagnosis of the patient on a controlled substance prescription. Questions of confidentiality are raised. What is the purpose of requiring the diagnosis? Is the diagnosis used to determine the legitimacy of the prescription?

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tex. Occ. Code § 107.001

§ 107.001. Short Title

This chapter may be cited as the Intractable Pain Treatment Act.

§ 107.002. Definitions

In this chapter:

(1) "Board" means the Texas State Board of Medical Examiners.

(2) "Intractable pain" means a state of pain for which:

(A) the cause of the pain cannot be removed or otherwise treated; and

(B) in the generally accepted course of medical practice, relief or cure of the cause of the pain:

(i) is not possible; or

(ii) has not been found after reasonable efforts.

(3) "Physician" means a physician licensed by the board.

§ 107.003. Nonapplicability of Chapter to Certain Chemically Dependent Persons

Except as provided by Subchapter C , this chapter does not apply to a person being treated by a physician for chemical dependency because of the person's use of a dangerous drug or controlled substance.

§ 107.051. Authority to Prescribe or Administer Dangerous Drug or Controlled Substance

Notwithstanding any other law, a physician may prescribe or administer a dangerous drug or controlled substance to a person in the course of the physician's treatment of the person for intractable pain.

§ 107.052. Limitations on Prescription or Administration of Dangerous Drug or Controlled Substance

This chapter does not authorize a physician to prescribe or administer to a person a dangerous drug or controlled substance:

(1) for a purpose that is not a legitimate medical purpose as defined by the board; and

(2) if the physician knows or should know the person is using drugs for a nontherapeutic purpose.

§ 107.053. Limitation on Authority of Hospital or Other Health Care Facility Regarding Use of Dangerous Drug or Controlled Substance

A hospital or other health care facility may not prohibit or restrict the use of a dangerous drug or controlled substance prescribed or administered by a physician who holds staff privileges at the hospital or facility for a person diagnosed and treated by a physician for intractable pain.

[CONITINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Attempts to provide a secure environment for physicians prescribing in their healthcare facility. However, this only applies to prescribing for intractable pain patients and not patients in general.

(-) *CRITERION 10:*
Implies opioids are not part of professional practice

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

§ 107.101. Patient

In this subchapter, "patient" includes a person who:

(1) is currently abusing a dangerous drug or controlled substance;

(2) is not currently abusing such a drug or substance but has a history of such abuse; or

(3) lives in an environment that poses a risk for misuse or diversion to illegitimate use of such a drug or substance.

§ 107.102. Authority To Treat

This chapter authorizes a physician to treat a patient with an acute or chronic painful medical condition with a dangerous drug or controlled substance to relieve the patient's pain using appropriate doses, for an appropriate length of time, and for as long as the pain persists.

§ 107.103. Duty to Monitor Patient

A physician who treats a patient under this subchapter shall monitor the patient to ensure that a prescribed dangerous drug or controlled substance is used only for the treatment of the patient's painful medical condition.

§ 107.104. Documentation and Consultation Required

To ensure that a prescribed dangerous drug or controlled substance is not diverted to another use and to ensure the appropriateness of the treatment of the patient's targeted symptoms, the physician shall:

(1) specifically document:

(A) the understanding between the physician and patient about the patient's prescribed treatment;

(B) the name of the drug or substance prescribed;

(C) the dosage and method of taking the prescribed drug or substance;

(D) the number of dose units prescribed; and

(E) the frequency of prescribing and dispensing the drug or substance; and

(2) consult with a psychologist, psychiatrist, expert in the treatment of addictions, or other health care professional, as appropriate.

[CONITINUED ON NEXT PAGE]

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management, which is authorized for all patients in §107.102.

(-) *CRITERION 14:*
Undue prescription requirements

COMMENT: Although it is reasonable to expect physicians to avoid knowingly issuing prescriptions that would contribute to diversion, an absolute requirement is unrealistic. What are the ramifications to the physician if diversion does occur despite monitoring?

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 5: Addresses fear of regulatory scrutiny*

[CONTINUED]

§ 107.151. Disciplinary Action Prohibited

A physician is not subject to disciplinary action by the board for prescribing or administering a dangerous drug or controlled substance in the course of treatment of a person for intractable pain.

§ 107.152. Authority of Board to Revoke or Suspend License

(a) This chapter does not affect the authority of the board to revoke or suspend the license of a physician who:

(1) prescribes, administers, or dispenses a drug or treatment:

(A) for a purpose that is not a legitimate medical purpose as defined by the board; and

(B) that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed;

(2) fails to keep a complete and accurate record of the purchase and disposal of:

(A) a drug listed in Chapter 481, Health and Safety Code; or

(B) a controlled substance scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970 *(21 U.S.C. Section 801* et seq.);

(3) writes a false or fictitious prescription for:

(A) a dangerous drug as defined by Chapter 483, Health and Safety Code;

(B) a controlled substance listed in a schedule under Chapter 481, Health and Safety Code; or

(C) a controlled substance scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970 *(21 U.S.C. Section 801* et seq.); or

(4) prescribes, administers, or dispenses in a manner inconsistent with public health and welfare:

(A) a dangerous drug as defined by Chapter 483, Health and Safety Code;

(B) a controlled substance listed in a schedule under Chapter 481, Health and Safety Code; or

(C) a controlled substance scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970 *(21 U.S.C. Section 801* et seq.).

(b) For purposes of Subsection (a)(2), the physician's records must include a record of:

(1) the date of purchase;

(2) the sale or disposal of the drug or substance by the physician;

(3) the name and address of the person receiving the drug or substance; and

(4) the reason for the disposal or dispensing of the drug or substance to the person.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

§ 107.201. Pain Treatment Review Committee

(a) The following individuals shall be appointed as a review committee on pain treatment:

(1) the attorney general or the attorney general's designee;

(2) a physician who practices at a public hospital in this state;

(3) a physician who practices at a private hospital in this state;

(4) a physician who practices in this state as a psychiatrist specializing in the treatment of addictive diseases;

(5) a probate court judge licensed to practice law in this state;

(6) a member of the governing board of the American Cancer Society, Texas Division, or the member's designee;

(7) a member of the governing board of the Texas Medical Association or the member's designee;

(8) a member of the governing board of the Texas Nurses Association or the member's designee;

(9) an officer of a public hospital in this state who is a member of the governing board of the Texas Hospital Association or the member's designee;

(10) an officer of a private hospital in this state who is a member of the governing board of the Texas Hospital Association or the member's designee; and

(11) a public member who is a resident of this state.

(b) The lieutenant governor and the speaker of the house of representatives shall each appoint five of the members described by Subsections (a)(2) through (11).

(c) The following individuals serve on the committee as nonvoting resource members and are appointed by the executive director of the agency the member represents:

(1) a pharmacist member of the Texas State Board of Pharmacy;

(2) a physician member of the Texas Medical Board;

(3) a nurse member of the Board of Nurse Examiners;

(4) a representative of the Department of Aging and Disability Services; and

(5) a representative of the narcotics regulatory programs of the Department of Public Safety.

(d) The committee shall study the relevant provisions in the laws of this state that relate to the administration of prescription medication, controlled substances, and the needs of patients for effective pain control and management.

The committee shall examine how the following statutes affect public health needs, the professional medical community, and persons affected by acute, chronic, or end-of-life pain:

(1) this chapter;

(2) Subtitles B, E, I, and J of this title; and

(3) Chapter 481, Health and Safety Code.

(e) The committee shall meet at least once every three months.

(f) Not later than September 1, 2008, the committee shall report any changes recommended to the statutes examined under Subsection (d) to the lieutenant governor, the speaker of the house of representatives, and the appropriate standing committees in the senate and the house of representatives that have jurisdiction over the issues studied by the committee.

(g) This section expires July 1, 2009.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Identifies provisions in state law as potential barriers to the appropriate use of opioid analgesics.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (board responsibility) to provide practitioners information/education about pain management.

Tex. Occ. Code § 153.014

§ 153.014. Information Provided to License Holders

At least once each biennium, the board shall provide to license holders information on:

(1) prescribing and dispensing pain medications, with particular emphasis on Schedule II and Schedule III controlled substances;

(2) abusive and addictive behavior of certain persons who use prescription pain medications;

(3) common diversion strategies employed by certain persons who use prescription pain medications, including fraudulent prescription patterns; and

(4) the appropriate use of pain medications and the differences between addiction, pseudo-addiction, tolerance, and physical dependence.

Tex. Occ. Code § 156.055

§ 156.055. Continuing Education in Pain Treatment

A physician licensed under this subtitle who submits an application for renewal of a license that designates a direct patient care practice and whose practice includes treating patients for pain is encouraged to include continuing medical education in pain treatment among the hours of continuing medical education completed to comply with Section 156.051(a)(2).

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (encouraging continuing education) to provide practitioners information/education about pain management.

Tex. Occ. Code § 164.053

§ 164.053. Unprofessional or Dishonorable Conduct

(a) For purposes of Section 164.052(a)(5), unprofessional or dishonorable conduct likely to deceive or defraud the public includes conduct in which a physician:

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(3) writes prescriptions for or dispenses to a person who:

(A) is known to be an abuser of narcotic drugs, controlled substances, or dangerous drugs; or

(B) the physician should have known was an abuser of narcotic drugs, controlled substances, or dangerous drugs;

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(c) Subsection (a)(3) does not apply to a person the physician is treating for:

(1) the person's use of narcotics after the physician notifies the board in writing of the name and address of the person being treated; or

(2) intractable pain under the Intractable Pain Treatment Act (Article 4495c, Revised Statutes).

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exemption of these patients nevertheless continues the prescribing restriction for all other patients with an addictive disease or history of addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Tex. Occ. Code § 551.003

§ 551.003. Definitions

In Chapters 551-566:

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(34) "Practitioner" means:

(A) a person licensed or registered to prescribe, distribute, administer, or dispense a prescription drug or device in the course of professional practice in this state, including a physician, dentist, podiatrist, or veterinarian but excluding a person licensed under this subtitle;

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(+) *CRITERION 3:*
Opioids are part of professional practice

Tex. Occ. Code § 554.014

§ 554.014. Information Provided to License Holders

At least once each biennium, the board shall provide to license holders information on:

(1) prescribing and dispensing pain medications, with particular emphasis on Schedule II and Schedule III controlled substances;

(2) abusive and addictive behavior of certain persons who use prescription pain medications;

(3) common diversion strategies employed by certain persons who use prescription pain medications, including fraudulent prescription patterns; and

(4) the appropriate use of pain medications and the differences between addiction, pseudo-addiction, tolerance, and physical dependence.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (board responsibility) to provide practitioners information/education about pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

37 TAC § 13.1

§ 13.1. Chapter Definitions

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise.

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(12) Individual practitioner--A physician, dentist, veterinarian, optometrist, podiatrist, or other individual licensed, registered, or otherwise permitted to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

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37 TAC § 13.73

§ 13.73. Form

(a) Use. A practitioner may issue a prescription for a Schedule II controlled substance only on an official Texas prescription form, which includes single or multiple copy forms. This subsection also applies to a prescription issued in an emergency situation.

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(-) *CRITERION 14:*
Undue prescription requirements

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

22 TAC § 170.1 - .3

§ 170.1. Purpose

The treatment of pain is a vital part of the practice of medicine. Patients look to physicians not only to cure disease, but also to try to relieve their pain. Physicians should be able to treat their patients' pain using sound clinical judgment without fear that the board will pursue disciplinary action. This Rule sets forth the board's policy for the proper treatment of pain. The board's intent is to protect the public and give guidance to physicians. The principles underlying this policy include:

(1) Pain is a medical condition that every physician sees regularly. It is an integral part of the practice of medicine. Patients deserve to have medical treatment for their pain, whether the pain is acute or chronic, mild or severe. The goal of pain management is to treat the patient's pain in relation to overall health, including physical function, psychological, social, and work-related factors.

(2) The regulatory atmosphere must support a physician's ability to treat pain, no matter how difficult the case, using whatever tools are most appropriate. Drugs, including opiates, are essential tools for the treatment of pain.

(3) The board is charged by the Legislature with the responsibility to assure that drugs are used in a therapeutic manner. A license to practice medicine gives a physician legal authority to prescribe drugs for pain. The physician has a duty to use that authority to help, and not to harm patients and the public.

(4) Harm can result when a physician does not use sound clinical judgment in using drug therapy. If the physician fails to apply sufficient drug therapy, the patient will likely suffer continued pain and may demonstrate relief-seeking behavior, known as pseudoaddiction. On the other hand, non-therapeutic drug therapy may lead to or contribute to abuse, addiction, and/or diversion of drugs. As with everything in the practice of medicine, physicians must be well informed of and carefully assess the risks and the benefits as they apply to each case.

(5) Physicians should not fear board action if they provide proper pain treatment. The board will not look solely at the quantity or duration of drug therapy. Proper pain treatment is not a matter of how much drug therapy is used, as long as that therapy is based on sound clinical judgment. Sound clinical judgment results from evidence-based medicine and/or the use of generally accepted standards.

(6) A physician can demonstrate sound clinical judgment by recording the physician's rationale for the treatment plan and maintaining medical records that are legible, complete, accurate and current for each patient.

(7) The extent of medical records should be reasonable for each case. A treatment plan for acute, episodic pain may note only the dosage and frequency of drugs prescribed and that no further treatment is planned.

(8) Treatment of chronic pain requires a reasonably detailed and documented plan to assure that the treatment is monitored. An explanation of the physician's rationale is especially required for cases in which treatment with scheduled drugs is difficult to relate to the patients objective physical, radiographic, or laboratory findings.

(9) The intent of these guidelines is not to impose regulatory burdens on the practice of medicine. Rather, these guidelines are intended to set forth those items expected to be done by any reasonable physician involved in the treatment of pain. The use of the word "shall" in these guidelines is used to identify those items a physician is required to perform in all such cases. The word "should" and the phrase "it is the responsibility of the physician" in these guidelines are used to identify those actions that a prudent physician will either do and document in the treatment of pain or be able to provide a thoughtful explanation as to why the physician did not do so.

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(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies pseudoaddiction as a possible consequence of inadequate pain management.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goals of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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§ 170.2. Definitions

In this Chapter:

(1) "Abuse" or "substance abuse"--the essential feature of substance abuse is a maladaptive pattern of substance use manifested by recurrent and significant adverse consequences related to the repeated use of substances.

(2) "Acute pain"--the normal, predicted, physiological response to a stimulus such as trauma, disease, and operative procedures. Acute pain is time limited.

(3) "Addiction"--a primary, chronic, neurobiological disease characterized by craving and compulsive use of drugs. Addiction is often characterized by impaired control over drug use, including taking more drugs more often than prescribed by a physician. It may also be characterized by continued use despite harm to oneself or others. Genetic, psychosocial, and environmental factors may influence the development and manifestation of addiction. Physical dependence and tolerance are normal physiological consequences of extended drug therapy for pain and, alone, do not indicate addiction.

(4) "Chronic pain"--a state in which pain persists beyond the usual course of an acute disease or healing of an injury. Chronic pain may be associated with a chronic pathological. process that causes continuous or intermittent pain over months or years.

(5) "Dangerous drugs"--medications defined by the Texas Dangerous Drug Act, Chapter 483, Texas Health and Safety Code. Dangerous drugs require a prescription, but are not included in the list of scheduled drugs. A dangerous drug bears the legend "Caution: federal law prohibits dispensing without a prescription" or "Prescription Only."

(6) "Diversion"--the use of drugs by anyone other than the person for whom the drug was prescribed.

(7) "Escalation"--increasing the dosage and/or frequency of the use of drugs.

(8) "Improper pain treatment"--includes over treatment, under treatment, no treatment, and the prescription of drugs for purposes other than the proper treatment of pain.

(9) "Non-therapeutic"--is defined in *§ 164.053(a)(5), Texas Occupations Code* and includes improper pain treatment.

(10) "Pain"--An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(11) "Physical dependence"--A state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, alone, does not indicate addiction.

(12) "Pseudoaddiction"--the iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

(13) "Scheduled drugs" (sometimes referred to as "Controlled Substances")--medications defined by the Texas Controlled Substances Act, Chapter 481, Texas Health and Safety Code. This Act establishes five categories, or schedules of drugs, based on risk of abuse and addiction. (Schedule I includes drugs that carry an extremely high risk of abuse and addiction and have no legitimate medical use. Schedule V includes drugs that have the lowest abuse/addiction risk).

(14) "Tolerance" (tachyphylaxis)--a physiological state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance does not necessarily occur during opioid treatment and does not, alone, indicate addiction.

(15) "Withdrawal"--the physiological and mental readjustment that accompanies discontinuation of a drug for which a person has established a physical dependence.

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(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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§ 170.3. Guidelines

(a) The Texas Medical Board will use these guidelines to assess a physician's treatment of pain.

(1) Evaluation of the patient.

(A) A physician is responsible for obtaining a medical history and a physical examination that includes a problem-focused exam specific to the chief presenting complaint of the patient.

(B) The medical record shall document the medical history and physical examination. In the case of chronic pain, the medical record should document:

(i) the nature and intensity of the pain,

(ii) current and past treatments for pain,

(iii) underlying or coexisting diseases and conditions,

(iv) the effect of the pain on physical and psychological function,

(v) any history and potential for substance abuse, and

(vi) the presence of one or more recognized medical indications for the use of a dangerous or scheduled drug.

(2) Treatment plan for chronic pain. The physician is responsible for a written treatment plan that is documented in the medical records. The medical record should include:

(A) How the medication relates to the chief presenting complaint of chronic pain;

(B) dosage and frequency of any drugs prescribed,

(C) further testing and diagnostic evaluations to be ordered,

(D) other treatments that are planned or considered,

(E) periodic reviews planned, and

(F) objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function.

(3) Informed consent. It is the physician's responsibility to discuss the risks and benefits of the use of controlled substances for the treatment of chronic pain with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. This discussion should be documented by either a written signed document maintained in the records or a contemporaneous notation included in the medical records. Discussion of risks and benefits should include an explanation of the:

(A) diagnosis;

(B) treatment plan;

(C) anticipated therapeutic results, including the realistic expectations for sustained pain relief and improved functioning and possibilities for lack of pain relief

(D) therapies in addition to or instead of drug therapy, including physical therapy or psychological techniques;

(E) potential side effects and how to manage them;

(F) adverse effects, including the potential for dependence, addiction, tolerance, and withdrawal; and

(G) potential for impairment of judgment and motor skills.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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(4) Agreement for treatment of chronic pain. A proper patient-physician relationship for treatment of chronic pain requires the physician to establish and inform the patient of the physician's expectations that are necessary for patient compliance. If the treatment plan includes extended drug therapy, the physician should consider the use of a written pain management agreement between the physician and the patient outlining patient responsibilities, including the following provisions:

(A) the physician may require laboratory tests for drug levels upon request;

(B) the physician may limit the number and frequency of prescription refills;

(C) only one physician will prescribe dangerous and scheduled drugs;

(D) only one pharmacy will be used for prescriptions, and

(E) reasons for which drug therapy may be discontinued (e.g. violation of agreement).

(5) Periodic review of the treatment of chronic pain.

(A) The physician should see the patient for periodic review at reasonable intervals in view of the individual circumstances of the patient.

(B) Periodic review should assess progress toward reaching treatment objectives, taking into consideration the history of medication usage, as well as any new information about the etiology of the pain.

(C) Each periodic visit shall be documented in the medical records.

(D) Contemporaneous to the periodic reviews, the physician should note in the medical records any adjustment in the treatment plan based on the individual medical needs of the patient.

(E) A physician should continue or modify the use of dangerous and scheduled drugs for pain management based on an evaluation of progress toward treatment objectives.

(i) Progress or the lack of progress in relieving pain should be documented in the patient's record.

(ii) Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, and/or improved quality of life.

(iii) Objective evidence of improved or diminished function should be monitored. Information from family members or other caregivers should be considered in determining the patient's response to treatment.

(iv) If the patient's progress is unsatisfactory, the physician should reassess the current treatment plan and consider the use of other therapeutic modalities.

(6) Consultation and Referral. The physician should refer a patient with chronic pain for further evaluation and treatment as necessary. Patients who are at-risk for abuse or addiction require special attention. Patients with chronic pain and histories of substance abuse or with co-morbid psychiatric disorders require even more care. A consult with or referral to an expert in the management of such patients should be considered in their treatment.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Allows for additional flexibility for physicians as long as their prescribing maintains the standards of good medical practice.

[CONTINUED]

(7) Medical records. The medical records shall document the physician's rationale for the treatment plan and the prescription of drugs for the chief complaint of chronic pain and show that the physician has followed these guidelines. Specifically the records should include:

(A) the medical history and the physical examination;

(B) diagnostic, therapeutic and laboratory results;

(C) evaluations and consultations;

(D) treatment objectives;

(E) discussion of risks and benefits;

(F) informed consent;

(G) treatments;

(H) medications (including date, type, dosage and quantity prescribed);

(I) instructions and agreements; and

(J) periodic reviews.

(b) It is not the board's policy to take disciplinary action against a physician solely for not adhering strictly to these guidelines if the physician's rationale for the treatment indicates sound clinical judgment documented in the medical records. Each case of prescribing for pain will be evaluated on an individual basis. The physician's conduct will be evaluated by considering:

(1) the treatment objectives, including any improvement in functioning,

(2) whether the drug used is pharmacologically recognized to be appropriate for the diagnosis as determined by a consensus of medical practitioners in the State or by recognized experts in the field for which the drug is being used,

(3) the patient's individual needs, and

(4) that some types of pain cannot be completely relieved.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

22 TAC § 281.7

§ 281.7. Grounds for Discipline for a Pharmacist License

(a) For the purposes of the Act, § 565.001(a)(2), "unprofessional conduct" shall include, but not be limited to:

(1) dispensing a prescription drug pursuant to a forged, altered, or fraudulent prescription;

(2) dispensing a prescription drug order pursuant to a prescription from a practitioner as follows:

(A) the dispensing of a prescription drug order not issued for a legitimate medical purpose or in the usual course of professional practice shall include the following:

(i) dispensing controlled substances or dangerous drugs to an individual or individuals in quantities, dosages, or for periods of time which grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature; or

(ii) dispensing controlled substances or dangerous drugs when the pharmacist knows or reasonably should have known that the controlled substances or dangerous drugs are not necessary or required for the patient's valid medical needs or for a valid therapeutic purpose;

(B) the provisions of subparagraph (A)(i) and (ii) of this paragraph are not applicable for prescriptions dispensed to persons with intractable pain in accordance with the requirements of the Intractable Pain Treatment Act, or to a narcotic drug dependent person in accordance with the requirements of *Title 21, Code of Federal Regulations, § 1306.07*, and the Regulation of Narcotic Drug Treatment Programs Act;

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22 TAC § 291.31

§ 291.31. Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

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(35) Practitioner--

(A) a person licensed or registered to prescribe, distribute, administer, or dispense a prescription drug or device in the course of professional practice in this state, including a physician, dentist, podiatrist, or veterinarian but excluding a person licensed under this subtitle;

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22 TAC § 291.34

§ 291.34. Records

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(ii) Prescription drug orders for Schedule II controlled substances shall be issued on an official prescription form as required by the Texas Controlled Substances Act, § 481.075, and be manually signed by the practitioner.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exemption of these patients nevertheless continues the prescribing restriction for all other patients with pain.

(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: "Grossly exceeds" implies there is a limit, but the limit is not specified; also, appears to inhibit off-label prescribing.

(-) *CRITERION 14:*
Undue prescription requirements

OTHER GOVERNMENTAL POLICIES

Pharmacy Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Texas State Board of Pharmacy
Position Statement on the Treatment of Pain

(+) *CRITERION 2:*
Pain management is part of medical practice

The Texas State Board of Pharmacy recognizes that quality care dictates that the people of the State of Texas have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages pharmacists to view effective pain management as a part of quality care for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All pharmacists should become knowledgeable about effective methods of pain treatment as well as statutory requirements for dispensing controlled substances.

(+) *CRITERION 4:*
Encourages pain management

Inadequate pain control may result from physicians' and pharmacists' lack of knowledge about pain management or an inadequate understanding of addiction. The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

The Board also recognizes that controlled substances are subject to abuse by individuals who seek them for mood altering and other psychological effects rather than their legitimate medical uses. When dispensing controlled substances, the pharmacist should be diligent in preventing them from being diverted from legitimate to illegitimate use. Tolerance and physical dependence are normal consequences of sustained use of these drugs and are not synonymous with psychological dependency (addiction). Psychological dependency is characterized by the compulsion to take the drug despite its harmful and destructive effect on the individual.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Pharmacists should not fear disciplinary action from the Board for dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain and sound clinical grounds. All such dispensing must be based on clear documentation of the patient's medical condition and pertinent discussions with the prescribing physician.

(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pain Treatment Education

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (medical education) to provide practitioners information/education about pain management.

Tex. Educ. Code § 51.309

§ 51.309. Pain Treatment Medical Education Course Work

(a) Each medical school shall determine the extent to which pain treatment medical education course work is meeting the instructional elements described in Subsection (b) and is offered to all students enrolled in medical schools.

(b) Pain treatment medical education course work should include instruction in:

(1) pain assessment in adults, children, and special populations, including elderly and impaired individuals;

(2) pain anatomy, physiology and pathophysiology, and pharmacology of opioid and nonopioid analgesic drugs, including pharmacokinetics and pharmacodynamics;

(3) the advantages and disadvantages of various methods of drug administration, side effects, treatment outcome, and the outcome of behavioral and other psychological therapy for pain;

(4) the psychological, social, economic, and emotional impact of malignant and nonmalignant acute and chronic pain on patients;

(5) indications for and outcomes of anesthetic and neurosurgical pain-relieving techniques, including nerve blocks and neuroaugmentative and neuroablative techniques; and

(6) the outcome of treatment of pain emanating from a damaged nervous system and neuropathic pain.

REGULATIONS

Licensing of Hospitals

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

25 TAC § 133.42

§ 133.42. Patient Rights

(a) Patient rights requirements for all hospitals.

(1) A hospital shall adopt, implement, and enforce a policy to ensure patients' rights. The written policy shall include:

(A) the right of the patient to the hospital's reasonable response to his or her requests and needs for treatment or service, within the hospital's capacity, its stated mission, and applicable law and regulation;

(B) the right of the patient to considerate and respectful care:

(i) the care of the patient includes consideration of the psychosocial, spiritual, and cultural variables that influence the perceptions of illness;

(ii) the care of the dying patient optimizes the comfort and dignity of the patient through:

(I) treating primary and secondary symptoms that respond to treatment as desired by the patient or surrogate decision maker;

(II) effectively managing pain;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospitals to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Standards for Licensure

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

40 TAC § 92.41

§ 92.41. Standards for Type A, Type B, and Type E Assisted Living Facilities

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(a) Employees.

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(4) Staff training. The facility must document that staff members are competent to provide personal care before assuming responsibilities and have received the following training.

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(D) Facilities that employ licensed nurses, certified nurse aides, or certified medication aides must provide annual in-service training, appropriate to their job responsibilities, from one or more of the following areas:

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(iii) geriatric pharmacology, including treatment for pain management, food and drug interactions, and sleep disorders;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (staff training) for assisted living facilities to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Licensing of Home and Community Support Services Agencies

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

40 TAC § 97.403

§ 97.403. Standards Specific to Agencies Licensed to Provide Hospice Services

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(h) The hospice must perform and make available to each client admitted for hospice services a client-specific comprehensive health assessment that identifies the client's need for hospice care and the client's need for medical, nursing, social, emotional, and spiritual care which includes, but is not limited to, the palliation and management of the terminal illness and related conditions and support services for clients and their families.

(1) The hospice must complete the comprehensive health assessment in a timely manner consistent with the client's immediate needs, but no later than seven calendar days after the start of hospice care.

(2) The comprehensive health assessment must include:

(A) input from the appropriate interdisciplinary team member(s) and an assessment of:

(i) each client's physical condition, including functional ability and nutritional status;

(ii) each client's pain and other symptoms and the management of discomfort and symptom relief;

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(C) a system of measures that captures significant outcomes that are essential to optimal hospice care, that are used in the care planning and coordination of services, and that are an essential part of the hospice's quality assessment and performance improvement program. The measures include, but are not limited to:

(i) pain;

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(i) A written plan of care must be established and maintained for each client admitted to the hospice program, and the care provided to a client must be in accordance with the plan. The plan of care must specify the care and services necessary to meet the client-specific needs identified in the comprehensive health assessment described in subsection (h) of this section, include all client care orders, reflect planned interventions for problems identified, and ensure that care and services are appropriate to the severity level of each client's and the client's family's specific needs.

(3) The plan must include:

(A) a comprehensive health assessment of the client's needs and identification of the services including the management of pain and symptom relief. The plan must state in detail the scope and frequency of services that are needed to meet the client's and family's needs;

(B) interventions to facilitate the management of pain and symptoms;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (comprehensive health assessment and care plan) for hospices to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

UTAH

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 58. Occupations and Professions; Chapter 37. Controlled Substances

- MEDICAL PRACTICE ACT
  Title 58. Occupations and Professions; Chapter 67. Utah Medical Practice Act

- OSTEOPATHIC PRACTICE ACT
  Title 58. Occupations and Professions; Chapter 68. Utah Osteopathic Medical Practice Act

- PHARMACY PRACTICE ACT
  Title 58. Occupations and Professions; Chapter 17b. Pharmacy Practice Act

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Commerce; R156. Occupational and Professional Licensing; R156-37. Utah Controlled Substances Act Rules

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Commerce; R156. Occupational and Professional Licensing; R156-67. Utah Medical Practice Act Rules

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Commerce; R156. Occupational and Professional Licensing; R156-68. Utah Osteopathic Medical Practice Act Rules

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Commerce; R156. Occupational and Professional Licensing; R156-17b. Pharmacy Practice Act Rules

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HARM REDUCTION PROGRAM
  Title 26. Utah Health Code; Chapter 1. Department of Health Organization

- PROFESSIONAL BOARD MODEL POLICY
  Commerce; R156. Occupational and Professional Licensing; R156-1. General Rules of the Division of Occupational and Professional Licensing

- PATIENT RECORDS
  Health; R432. Health Systems Improvement, Licensing; R432-750. Hospice Rule

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act		●						
Osteopathic Practice Act		●						
Pharmacy Practice Act			●					
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Harm Reduction Program								●
Professional Board Model Policy		●	●	●	●	●	●	●
Patient Records								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act				●				
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Harm Reduction Program[1]								
Professional Board Model Policy								●
Patient Records[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

UTAH

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

Utah Code Ann. § 58-37-2

§ 58-37-2. Definitions

(1) As used in this chapter:

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(jj) "Practitioner" means a physician, dentist, veterinarian, pharmacist, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis a controlled substance in the course of professional practice or research in this state.

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Utah Code Ann. § 58-37-6

§ 58-37-6. License to manufacture, produce, distribute, dispense, administer, or conduct research — Issuance by department — Denial, suspension, or revocation — Records required — Prescriptions

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(B) A Schedule II controlled substance may not be filled in a quantity to exceed a one-month's supply, as directed on the daily dosage rate of the prescriptions.

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(i) A practitioner licensed under this chapter may not prescribe or administer dosages of a controlled substance in excess of medically recognized quantities necessary to treat the ailment, malady, or condition of the ultimate user.

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(-) *CRITERION 12:*
Medical decisions are restricted

***CATEGORY C*:**
Restrictions regarding quantity prescribed or dispensed

COMMENT: "Excess" implies there is a limit, but the limit is not specified.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

Utah Code Ann. § 58-67-102

§ 58-67-102. Definitions

In addition to the definitions in Section 58-1-102, as used in this chapter:

(8) "Practice of medicine" means:

(a) to diagnose, treat, correct, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, or to attempt to do so, by any means or instrumentality, and by an individual in Utah or outside the state upon or for any human within the state;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

UTAH

STATUTES

Osteopathic Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Utah Code Ann. § 58-68-102

§ 58-68-102. Definitions

In addition to the definitions in Section 58-1-102, as used in this chapter:

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(8) "Practice of osteopathic medicine" means:

(a) to diagnose, treat, correct, administer anesthesia, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, physical or mental, real or imaginary, or to attempt to do so, by any means or instrumentality, which in whole or in part is based upon emphasis of the importance of the musculoskeletal system and manipulative therapy in the maintenance and restoration of health, by an individual in Utah or outside of the state upon or for any human within the state, except that conduct described in this Subsection (8)(a) that is performed by a person legally and in accordance with a license issued under another chapter of this title does not constitute the practice of medicine;

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(+) *CRITERION 2:*
Pain management is part of medical practice

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Utah Code Ann. § 58-17b-102

§ 58-17b-102. Definitions

In addition to the definitions in Section 58-1-102, as used in this chapter:

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(59) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

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(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

UTAH

STATUTES

Harm Reduction Program

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Utah Code Ann. § 26-1-36

§ 26-1-36. Duty to establish program to reduce deaths and other harm from prescription opiates used for chronic noncancer pain

(1) As used in this section, "opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability.

(2) In addition to the duties listed in *Section 26-1-30*, the department shall develop and implement a two-year program in coordination with the Division of Professional Licensing, the Utah Labor Commission, and the Utah attorney general, to:

(a) investigate the causes of and risk factors for death and nonfatal complications of prescription opiate use and misuse in Utah for chronic pain by utilizing the Utah Controlled Substance Database created in *Section 58-37-7.5*;

(b) study the risks, warning signs, and solutions to the risks associated with prescription opiate medications for chronic pain, including risks and prevention of misuse and diversion of those medications; and

(c) provide education to health care providers, patients, insurers, and the general public on the appropriate management of chronic pain, including the effective use of medical treatment and quality care guidelines that are scientifically based and peer reviewed.

(3) The department shall report on the development and implementation of the program required in Subsection (2) to the legislative Health and Human Services Interim Committee and the legislative Business and Labor Interim Committee no later than the November interim meetings in 2007 and 2008. Each report shall include:

(a) recommendations on:

(i) use of the Utah Controlled Substance Database created in *Section 58-37-7.5* to identify and prevent:

(A) misuse of opiates;

(B) inappropriate prescribing; and

(C) adverse outcomes of prescription opiate medications;

(ii) interventions to prevent the diversion of prescription opiate medications; and

(iii) medical treatment and quality care guidelines that are:

(A) scientifically based; and

(B) peer reviewed; and

(b) (i) a measure of results against expectations under the program as of the date of the report; and

(ii) an analysis of the application of the program, use of the appropriated funds, and the impact and results of the use of the funds.

(4) The report provided under Subsection (3) for the 2008 interim shall also provide a final cumulative analysis of the measurable effectiveness of the program implemented under this section.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (educational program) to provide practitioners information/education about pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to determine the impact of the educational component of this program on pain management and patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

UTAH

REGULATIONS

Professional Board Model Policy

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY C:
Conflicting or inconsistent policies or provisions

COMMENT: Contradicts the flexibility standards inherent in the *Model Policy*.

U.A.C. R156-1-502

R156-1-502. Unprofessional Conduct.

"Unprofessional conduct" includes:
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(6) failing, as a prescribing practitioner, to follow the "Model Policy for the Use of Controlled Substances for the Treatment of Pain", 2004, established by the Federation of State Medical Boards, which is hereby adopted and incorporated by reference.

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

UTAH

REGULATIONS

Professional Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

1. Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

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(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Professional Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

3. Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

a. urine/serum medication levels screening when requested;
b. number and frequency of all prescription refills; and
c. reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

5. Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records—The physician should keep accurate and complete records to include

a. the medical history and physical examination,
b. diagnostic, therapeutic and laboratory results,
c. evaluations and consultations,
d. treatment objectives,
e. discussion of risks and benefits,
f. informed consent,
g. treatments,
h. medications (including date, type, dosage and quantity prescribed),
i. instructions and agreements and
j. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Professional Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

7. Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to *the Physicians Manual of the U.S. Drug Enforcement Administration* and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury**,** or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Patient Records

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (record keeping policies and procedures) for hospices to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

U.A.C. R432-750-12

R432-750-12. Patient Records.

(1) The administrator shall develop and implement record keeping policies and procedures that address the use of patient records by authorized staff, content, confidentiality, retention, and storage.

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(3) Each patient's record shall contain at least the following information:

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(h) a signed, dated patient assessment which includes the following:

(i) a description of the patient's functional limitations;

(ii) a physical assessment noting chronic or acute pain and other physical symptoms and their management;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

VT

VERMONT

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 18. Health; Part 5. Foods and Drugs
  Chapter 84. Possession and Control of Regulated Drugs
  Chapter 84A. Vermont Prescription Monitoring Program

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 26. Professions and Occupations; Chapter 23. Medicine and Surgery

- OSTEOPATHIC PRACTICE ACT
  Title 26. Professions and Occupations; Chapter 33. Osteopathy

- PHARMACY PRACTICE ACT
  Title 26. Professions and Occupations; Chapter 36. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Agency 13. Agency of Human Services; Sub-Agency 140. Department of Health;
  Chapter 011. Regulated Drug Rule

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Agency13. Agency of Human Services; Sub-Agency 141. Board of Medical Practice;
  Chapter 001. Rules of the Board of Medical Practice

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Agency 04. Secretary of State; Sub-Agency 030. Office of Professional Regulation;
  Chapter 220. Rules of the Board of Osteopathic Physicians and Surgeons

- PHARMACY BOARD REGULATIONS
  Agency 04. Secretary of State; Sub-Agency 030. Office of Professional Regulation;
  Chapter 230. Board of Pharmacy Administrative Rules

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Vermont Board of Medical Practice. *Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: December 7, 2005.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- BILL OF RIGHTS FOR HOSPITAL PATIENTS
  Title 18. Health; Part 3. Hospitals, Health Centers, Nursing Homes; Chapter 42. Bill of Rights for Hospital Patients

- NURSING HOME RESIDENT BILL OF RIGHTS
  Title 33. Human Services; Part 5. Programs and Services for Vulnerable Adults; Chapter 73. Nursing Home Residents' Bill of Rights

- HOMES FOR THE TERMINALLY ILL
  Agency 13. Agency of Human Services; Sub-Agency 110. Department of Aging and Disabilities; Chapter 006. Licensing Regulations for Homes of the Terminally Ill

- OPIATE ADDICTION TREATMENT
  Agency 13. Agency of Human Services; Sub-Agency 140. Department of Health; Chapter 062. Opiate Addiction Treatment Rules

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					●
Medical Practice Act[1]								
Osteopathic Practice Act		●						
Pharmacy Practice Act			●					
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances								●
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board			●					
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Bill of Rights for Hospital Patients								●
Nursing Home Resident Bill of Rights								●
Homes for the Terminally Ill								●
Opiate Addiction Treatment							●	●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

Provisions that may *IMPEDE* pain management

Criteria	9 Opioids are a last resort	10 Implies opioids are not part of professional practice	11 Physical dependence or analgesic tolerance confused with "addiction"	12 Medical decisions are restricted	13 Length of prescription validity is restricted	14 Undue prescription requirements	15 Other provisions that may impede pain management	16 Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances								●
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board					●			
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Bill of Rights for Hospital Patients[1]								
Nursing Home Resident Bill of Rights[1]								
Homes for the Terminally Ill[1]								
Opiate Addiction Treatment[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

18 V.S.A. § 4201

§ 4201. Definitions

As used in this chapter, unless the context otherwise requires:

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(24) "Practitioner" includes a physician, dentist, veterinarian, surgeon or any other person who may be lawfully entitled under this chapter to distribute, dispense, prescribe, or administer regulated drugs to patients.

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18 V.S.A. § 4281

§ 4281. Legislative intent

The general assembly recognizes the important public health benefits of the legal medical use of controlled substances and also the significant risk to public health that can arise due to the abuse of those substances. It is the intent of this chapter to create the Vermont prescription monitoring system, which will provide an electronic database and reporting system for electronic monitoring of prescriptions for Schedules II, III, and IV controlled substances, as defined in 21 C.F.R. Part 1308, as amended and as may be amended, to promote the public health through enhanced opportunities for treatment for and prevention of abuse of controlled substances, without interfering with the legal medical use of those substances.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (record keeping policies and procedures) for hospices to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

STATUTES

Osteopathic Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

26 V.S.A. § 1750

§ 1750. Definitions

As used in this chapter:

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(10) "Practice of osteopathic medicine" means the diagnosis, treatment, operation or prescription for any human disease, pain, injury, deformity or other physical or mental condition, which practice is based in part upon educational standards and requirements which emphasize the importance of the neuromusculoskeletal structure and manipulative treatment in the maintenance and restoration of health.

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(+) *CRITERION 2:*
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

26 V.S.A. § 2022

§ 2022. Definitions

As used in this chapter:

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(15) "Practitioner" shall mean a physician, dentist, nurse, veterinarian, scientific investigator, or other person (other than pharmacists) licensed by this state or adjoining states or the province of Quebec and permitted by such license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research in their respective state or province.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

VERMONT

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Although the policy clearly states that "Recommended Individual Therapeutic Dosage" has no implication for medical practice, the term nevertheless establishes a legal concept that has undefined implications for the practitioner who does not conform to the dosages.

CVR 13-140-011

13 140 011. Regulated Drugs Rule

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VIII. Dosages and Doses

(a) Preface

18 V.S.A., § 4234 directs the Board of Health to establish a Recommended Individual Therapeutic Dosage for selected stimulants, depressants, and narcotic drugs.

The Board of Health has done so, but wishes to formally preface this submission with an explanation of these dosages.

The Recommended Individual Therapeutic Dosage is not a medical or pharmacologic concept with any implication for medical practice. Instead, it is a legal concept established only for this statute.

In clinical practice, there is no one recommended dose and no predetermined maximum dose for most drugs. Most drugs have more than one legitimate use, and doses vary accordingly. The Board of Health does not intend to guide or restrict medical practice in any way. These doses do not represent a standard of practice.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that adequate pain management depends on a practitioner's ability to adjust medication amounts based on the individual needs of the patient, and may not be achieved with predetermined maximum doses.

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

CVR 04-030-230

Section 8. Abbreviations And Definitions

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8.2.33 "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and administer Drugs in the course of professional practice.

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19.3.2. No prescription for a Schedule II controlled drug shall be filled more than 10 days after issuance of the prescription.

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(-) *CRITERION 13:*
Length of prescription validity is restricted

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Federation of State Medical Boards of the United States, Inc.

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., May 2004.

Introduction

The Federation of State Medical Boards (the Federation) is committed to assisting state medical boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the Federation undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policy encouraging adequate treatment, including use of opioids when appropriate for patients with pain. The Federation thanks the Robert Wood Johnson Foundation for awarding a grant in support of the original project, and the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine, & Ethics, and the University of Wisconsin Pain & Policy Studies Group for their contributions.

Since adoption in April 1998, the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The Model Guidelines have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the Model Guidelines. 1 Despite increasing concern in recent years regarding the abuse and diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated. Many terminally ill patients unnecessarily experience moderate to severe pain in the last weeks of life.2 The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in state pain policies.3 Circumstances that contribute to the prevalence of undertreated pain include: (1) lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of addiction and dependence; and (4) lack of understanding of regulatory policies and processes. Adding to this problem is the reality that the successful implementation of state medical board pain policy varies among jurisdictions.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

In April 2003, the Federation membership called for an update to its Model Guidelines to assure currency and adequate attention to the undertreatment of pain. The goal of the revised model policy is to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The title of the policy has been changed from Model Guidelines to *Model Policy* to better reflect the practical use of the document.

The *Model Policy* is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. This policy is not meant to constrain or dictate medical decision-making.

Through this initiative, the Federation aims to achieve more consistent policy in promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of regulatory scrutiny. In promulgating this *Model Policy*, the Federation strives to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion.

State medical boards are encouraged, in cooperation with their state's attorney general, to evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. Accordingly, this *Model Policy* has been revised to emphasize the professional and ethical responsibility of the physician to assess patients' pain as well as to update references and definitions of key terms used in pain management.

The *Model Policy* is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations.

1. As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's Model Guidelines for the Use of Controlled Substances for the Treatment of Pain and two (2) states have formally endorsed the Model Guidelines.

2. SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: JAMA, 274(20) (1995): p. 1591-1598.

3. A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, J. of Law, Medicine, and Ethics, 31 (2003): p. 128.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Identifies the possibility of restrictive policies as an important barrier to the appropriate use of opioid analgesics.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(CONTINUED)

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble
The Vermont Board of Medical Practice recognizes that principles of quality medical practice dictate that patients have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines
The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including urine/serum medication levels screening when requested; number and frequency of all prescription refills; and reasons for which drug therapy may be discontinued (e.g., violation of agreement).

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards to good medical practice.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements and
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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Section III: Definitions
For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Bill of Rights for Hospital Patients

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospitals to ensure that pain management is an essential part of patient care.

18 V.S.A. § 1852

§ 1852. Patients' bill of rights; adoption

(a) The general assembly hereby adopts the "Bill of Rights for Hospital Patients" as follows:

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(16) The patient has the right to receive professional assessment of pain and professional pain management.

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STATUTES

Nursing Home Resident Bill of Rights

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

33 V.S.A. § 7301

§ 7301. Nursing home residents' bill of rights

The general assembly hereby adopts the Nursing Home Residents' Bill of Rights as follows:

(1) The governing body of the facility shall establish written policies regarding the rights and responsibilities of residents and, through the administrator, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures shall be made available to residents, to any guardians, next of kin, reciprocal beneficiaries, sponsoring agency, or representative payees selected pursuant to subsection 205(j) of the Social Security Act, and Subpart Q of 20 CFR Part 404, and to the public.

(2) The staff of the facility shall ensure that, at least, each individual admitted to the facility:

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(T) is provided with professional assessment of pain and its management.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for nursing homes to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

VERMONT

REGULATIONS

Homes for the Terminally Ill

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

CVR 13-110-006

13 110 006. Licensing Regulations for Homes for the Terminally Ill

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5.9 Medication Management

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(e) Staff responsible for assisting residents with medications must receive training from the registered nurse in the following areas before assisting with any medications:

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(5) Pain assessment and management.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (staff training) for homes for the terminally ill to ensure that pain management is an essential part of patient care.

REGULATIONS

Opiate Addiction Treatment

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

CVR 13-140-062

13 140 062. Opiate Addition Treatment Rules

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D. Pain Management in Maintenance Patients

1. Management of chronic pain in the methadone-maintained patient includes consultation with a specialist in pain medicine when possible and appropriate.

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D. Patients with Chronic Pain

1. Programs shall make careful diagnostic distinctions between the physical dependence associated with chronic administration of opiates for relief of pain and the disease of opiate addiction. Apparent drug-seeking behaviors, typically associated with the disease of chronic opiate addiction, may occur as a response to inadequately treated or prolonged pain ("pseudo-addiction"). The physical dependence and tolerance to opiates seen in some chronic pain patients is an expected physiological response to pharmacological therapy and does not support a diagnosis of active opiate addiction.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for OTP staff to refer methadone-maintained patients who have chronic pain for treatment of their pain.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies pseudoaddiction as an important barrier to the appropriate use of opioid analgesics.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

VA

VIRGINIA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 54.1. Professions and Occupations; Subtitle III. Professions and Occupations Regulated by Boards Within the Department of Health Professions; Chapter 34. Drug Control Act

- MEDICAL PRACTICE ACT
  Title 54.1. Professions and Occupations; Subtitle III. Professions and Occupations Regulated by Boards Within the Department of Health Professions; Chapter 29. Medicine and Other Healing Arts

- PHARMACY PRACTICE ACT
  Title 54.1. Professions and Occupations; Subtitle III. Professions and Occupations Regulated by Boards Within the Department of Health Professions; Chapter 33. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Title 18. Professional Occupational Licensing; Agency Number 110. Board of Pharmacy

- MEDICAL BOARD REGULATIONS
  Title 18. Professional Occupational Licensing; Agency Number 85. Board of Medicine

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 18. Professional Occupational Licensing; Agency Number 110. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Virginia Board of Medicine. *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: July 24, 2004.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- INJUNCTION AGAINST ASSISTED SUICIDE
  Title 8.01. Civil Remedies and Procedures; Chapter 24. Injunctions

- REGULATIONS FOR THE LICENSURE OF HOSPICE
  Title 12. Health; Agency Number 5. Department of Health; Hospitals, Nursing Homes, and Related Institutions and Services; Chapter 391. Regulations for the Licensure of Hospice; Part II. Administrative Services

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●			●		
Medical Practice Act		●				●		●
Pharmacy Practice Act			●					
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board		●						
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Injunction Against Assisted Suicide								●
Regulations for the Licensure of Hospice								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Injunction Against Assisted Suicide[1]								
Regulations for the Licensure of Hospice[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

VIRGINIA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Va. Code Ann. § 54.1-3401

§ 54.1-3401. Definitions

As used in this chapter, unless the context requires a different meaning:

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"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to *§ 54.1-2957.01*, licensed physician assistant pursuant to *§ 54.1-2952.1*, pharmacist pursuant to *§ 54.1-3300*, TPA-certified optometrist pursuant to Article 5 (*§ 54.1-3222* et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to, a controlled substance in the course of professional practice or research in the Commonwealth.

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(+) *CRITERION 3:* *Opioids are part of professional practice*

Va. Code Ann. § 54.1-3408.1

§ 54.1-3408.1. Prescription in excess of recommended dosage in certain cases

In the case of a patient with intractable pain, a physician may prescribe a dosage in excess of the recommended dosage of a pain relieving agent if he certifies the medical necessity for such excess dosage in the patient's medical record. Any person who prescribes, dispenses or administers an excess dosage in accordance with this section shall not be in violation of the provisions of this title because of such excess dosage, if such excess dosage is prescribed, dispensed or administered in good faith for accepted medicinal or therapeutic purposes.

Nothing in this section shall be construed to grant any person immunity from investigation or disciplinary action based on the prescription, dispensing or administration of an excess dosage in violation of this title.

(+) *CRITERION 6:* *Prescription amount alone does not determine legitimacy*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

VIRGINIA

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

Va. Code Ann. § 54.1-2900

§ 54.1-2900. Definitions

As used in this chapter, unless the context requires a different meaning:

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"Practice of medicine or osteopathic medicine" means the prevention, diagnosis and treatment of human physical or mental ailments, conditions, diseases, pain or infirmities by any means or method.

. . .

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to communicate to practitioners about existing pain management standards.

Va. Code Ann. § 54.1-2912.2

§ 54.1-2912.2. Board may endorse certain document

In the furtherance of its responsibility to ensure continued practitioner competency, the Board of Medicine may endorse the Medical Society of Virginia's Guidelines for the Use of Opioids in the Management of Chronic, Non-Cancer Pain, developed and adopted in 1997.

For the purpose of this section, *"endorse"* means to publicize and distribute such guidelines as providing an appropriate standard of care; however, the Board's endorsement shall not be construed to mean that the guidelines must be followed or are regulations or are in any way intended to be enforceable law.

Va. Code Ann. § 54.1-2971.01

§ 54.1-2971.01. Prescription in excess of recommended dosage in certain cases

A. Consistent with § 54.1-3408.1, a physician may prescribe a dosage of a pain-relieving agent in excess of the recommended dosage upon certifying the medical necessity for the excess dosage in the patient's medical record. Any practitioner who prescribes, dispenses or administers an excess dosage in accordance with this section and § 54.1-3408.1 shall not be in violation of the provisions of this title because of such excess dosage, if such excess dosage is prescribed, dispensed or administered in good faith for recognized medicinal or therapeutic purposes.

B. The Board of Medicine shall advise physicians of the provisions of this section and § 54.1-3408.1.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

Va. Code Ann. § 54.1-3303

§ 54.1-3303. Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by a licensed nurse practitioner pursuant to *§ 54.1-2957.01*, a licensed physician assistant pursuant to *§ 54.1-2952.1*, or a TPA-certified optometrist pursuant to Article 5 (*§ 54.1-3222* et seq.) of Chapter 32 of this title. The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

VIRGINIA

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

18 VAC 85-20-10.

18 VAC 85-20-10. Definitions.

A. The following words and terms when used in this chapter shall have the meanings ascribed to them in *§ 54.1-2900 of the Code of Virginia*:

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Practice of medicine or osteopathic medicine (by reference: means the prevention, diagnosis and treatment of human physical or mental ailments, conditions, diseases, pain or infirmities by any means or method)

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Federation of State Medical Boards of the United States, Inc.

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., May 2004.

Introduction

The Federation of State Medical Boards (the Federation) is committed to assisting state medical boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the Federation undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policy encouraging adequate treatment, including use of opioids when appropriate for patients with pain. The Federation thanks the Robert Wood Johnson Foundation for awarding a grant in support of the original project, and the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine, & Ethics, and the University of Wisconsin Pain & Policy Studies Group for their contributions.

Since adoption in April 1998, the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The Model Guidelines have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the Model Guidelines. 1 Despite increasing concern in recent years regarding the abuse and diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated. Many terminally ill patients unnecessarily experience moderate to severe pain in the last weeks of life.2 The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in state pain policies.3 Circumstances that contribute to the prevalence of undertreated pain include: (1) lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of addiction and dependence; and (4) lack of understanding of regulatory policies and processes. Adding to this problem is the reality that the successful implementation of state medical board pain policy varies among jurisdictions.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

In April 2003, the Federation membership called for an update to its Model Guidelines to assure currency and adequate attention to the undertreatment of pain. The goal of the revised model policy is to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The title of the policy has been changed from Model Guidelines to *Model Policy* to better reflect the practical use of the document.

The *Model Policy* is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. This policy is not meant to constrain or dictate medical decision-making.

Through this initiative, the Federation aims to achieve more consistent policy in promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of regulatory scrutiny. In promulgating this *Model Policy*, the Federation strives to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion.

State medical boards are encouraged, in cooperation with their state's attorney general, to evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. Accordingly, this *Model Policy* has been revised to emphasize the professional and ethical responsibility of the physician to assess patients' pain as well as to update references and definitions of key terms used in pain management.

The *Model Policy* is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations.

1. As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's Model Guidelines for the Use of Controlled Substances for the Treatment of Pain and two (2) states have formally endorsed the Model Guidelines.

2. SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: JAMA, 274(20) (1995): p. 1591-1598.

3. A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, J. of Law, Medicine, and Ethics, 31 (2003): p. 128.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Identifies the possibility of restrictive policies as an important barrier to the appropriate use of opioid analgesics.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

VIRGINIA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

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Model Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble
The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

VIRGINIA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards to good medical practice.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines
The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including urine/serum medication levels screening when requested; number and frequency of all prescription refills; and reasons for which drug therapy may be discontinued (e.g., violation of agreement).

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements and
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

VIRGINIA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Section III: Definitions
For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

VIRGINIA

STATUTES

Injunction Against Assisted Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Va. Code Ann. § 8.01-622.1

§ 8.01-622.1. Injunction against assisted suicide; damages; professional sanctions

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E. Nothing in this section shall be construed to limit or conflict with § 54.1-2971.01 or the Health Care Decisions Act (§ 54.1-2981 et seq.). This section shall not apply to a licensed health care provider who (i) administers, prescribes or dispenses medications or procedures to relieve another person's pain or discomfort and without intent to cause death, even if the medication or procedure may hasten or increase the risk of death, or (ii) withholds or withdraws life-prolonging procedures as defined in § 54.1-2982. This section shall not apply to any person who properly administers a legally prescribed medication without intent to cause death, even if the medication may hasten or increase the risk of death.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

VIRGINIA

REGULATIONS

Regulations for the Licensure of Hospice

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written policies and procedures) for hospices to ensure that pain management is an essential part of patient care.

12 VAC 5-391-190.

12 VAC 5-391-190. Written policies and procedures.

A. The hospice program shall implement written policies and procedures approved by the governing body.

B. All policies and procedures shall be reviewed at least annually, with recommended changes submitted to the governing body for approval, as necessary.

C. Administrative and operational policies and procedures shall include, but are not limited to:

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6. Pain assessment and management;

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12 VAC 5-391-240.

12 VAC 5-391-240. Patient rights.

A. The hospice program shall establish and implement written policies and procedures regarding the rights of patients. A copy of the patient's rights shall be displayed in the hospice office for public review.

B. Written procedures to implement the policies shall ensure that each patient is:

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5. Assured the right to participate in the planning of his care, including appropriate assessment and management of pain and the right to refuse services;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes the patient's right to request or reject different types of treatments.

12 VAC 5-391-260.

12 VAC 5-391-260. Quality improvement.

A. The hospice program shall implement an on-going, comprehensive, integrated, self-assessment program of the quality and appropriateness of care provided, including services provided under contract. The quality improvement program shall address actual patient outcomes (results of care), clinical, administrative, and cost-of-care issues. The findings shall be used to correct identified problems and revise policies and practices, as necessary. Exclusive concentration on administrative or cost-of-care issues does not fulfill this requirement.

B. The following areas shall be evaluated to identify unacceptable or unexpected trends or occurrences that influence patient outcomes (results of care):

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6. Appropriateness and effectiveness of pain management;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility and various mechanisms for hospices to ensure that pain management is an essential part of patient care.

12 VAC 5-381-280.

12 VAC 5-381-280. Client record system.

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F. An accurate and complete client record shall be maintained for each client receiving services and shall include, but shall not be limited to:

10. A medical plan of care including appropriate assessment and pain management;

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Regulations for the Licensure of Hospice

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes mechanisms for hospices to ensure that pain management is an essential part of patient care .

12 VAC 5-391-320.

12 VAC 5-391-320. Plan of care.

A. At the time of a patient's admission to the hospice program, the IDG shall develop and maintain a plan of care, including but not limited to:

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4. A comprehensive assessment of pain, as warranted by the patient's condition and the scope of services provided by the hospice program;

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12 VAC 5-391-330.

12 VAC 5-391-330. Medical direction.

A. There shall be a medical director, who shall be a physician licensed by the Virginia Board of Medicine, responsible for the overall direction and management of the medical component of care. The individual shall have training and experience in the psychological and medical needs of the terminally ill.

B. The medical director shall have admitting privileges at one or more hospitals and nursing facilities that provide inpatient service to the hospice program's patients.

C. The duties and responsibilities of the medical director shall include at least the following:

1. Consulting with attending physicians regarding pain and symptom management;

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

WA

WASHINGTON

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 69. Food, Drugs, Cosmetics, and Poisons; Chapter 69.50. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Title 18. Businesses and Professions;
  Chapter 18.71. Physicians
  Chapter 18.72. Medical Disciplinary Board

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Title 18. Businesses and Professions; Chapter 18.57. Osteopathy – Osteopathic Medicine and Surgery

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 18. Businesses and Professions; Chapter 18.64. Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Title 246. Department of Health; Chapter 887. Pharmacy; Regulations Implementing the Uniform Controlled Substances Act

- MEDICAL BOARD REGULATIONS
  Title 246. Department of Health; Chapter 919. Medical Quality Assurance Commission

- OSTEOPATHIC BOARD REGULATIONS
  Title 246. Department of Health; Chapter 853. Osteopathic Physicians and Surgeons

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 246. Department of Health; Chapters 856-907

OTHER GOVERNMENTAL POLICIES

- DEPARTMENT OF HEALTH GUIDELINE
  Department of Health. *Guidelines for Management of Pain*. Adopted: April 18, 1996.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- PROFESSIONAL PRACTICE

  Title 18. Businesses and Professions; Chapter 18.130. Regulation of Health Professions – Uniform Disciplinary Act

- HOSPICE PLAN OF CARE

  Title 246. Department of Health; Chapter 335. In-Home Services Agencies; Part 1. Requirements for In-Home Services Agencies Licensed to Provide Home Health, Home Care, Hospice, and Hospice Care Center Services

- ADULT RESIDENTIAL CARE SERVICE

  Title 388. Department of Social and Health Services; Chapter 110. Contracted Residential Care Services; Part III. Enhanced Adult Residential Care

WA

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act		●	●					
Medical Practice Act		●						
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board		●		●	●	●		●
Osteopathic Board		●		●	●			●
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Dept. of Health Guideline			●		●		●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Professional Practice								●
Hospice Plan of Care								●
Adult Residential Care Service								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

WA

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Dept. of Health Guideline	•							•
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Professional Practice[1]								
Hospice Plan of Care[1]								
Adult Residential Care Service[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Rev. Code Wash. (ARCW) § 69.50.101

§ 69.50.101. Definitions

Unless the context clearly requires otherwise, definitions of terms shall be as indicated where used in this chapter:

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(w) "Practitioner" means:

(1) A physician under chapter 18.71 RCW, a physician assistant under chapter 18.71A RCW, an osteopathic physician and surgeon under chapter 18.57 RCW, an optometrist licensed under chapter 18.53 RCW who is certified by the optometry board under *RCW 18.53.010* subject to any limitations in *RCW 18.53.010,* a dentist under chapter 18.32 RCW, a podiatric physician and surgeon under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a registered nurse, advanced registered nurse practitioner, or licensed practical nurse under chapter 18.79 RCW, a pharmacist under chapter 18.64 RCW or a scientific investigator under this chapter, licensed, registered or otherwise permitted insofar as is consistent with those licensing laws to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of their professional practice or research in this state.

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(+) *CRITERION 3:*
Opioids are part of professional practice

Rev. Code Wash. (ARCW) § 69.50.308

§ 69.50.308. Prescriptions

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(g) A practitioner may dispense or deliver a controlled substance to or for an individual or animal only for medical treatment or authorized research in the ordinary course of that practitioner's profession. Medical treatment includes dispensing or administering a narcotic drug for pain, including intractable pain.

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(+) *CRITERION 2:*
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

Rev. Code Wash. (ARCW) § 18.71.011

§ 18.71.011. Definition of practice of medicine — Engaging in practice of chiropractic prohibited, when

A person is practicing medicine if he does one or more of the following:

(1) Offers or undertakes to diagnose, cure, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;

(2) Administers or prescribes drugs or medicinal preparations to be used by any other person;

(3) Severs or penetrates the tissues of human beings;

(4) Uses on cards, books, papers, signs or other written or printed means of giving information to the public, in the conduct of any occupation or profession pertaining to the diagnosis or treatment of human disease or conditions the designation "doctor of medicine", "physician", "surgeon", "m.d." or any combination thereof unless such designation additionally contains the description of another branch of the healing arts for which a person has a license: PROVIDED HOWEVER, That a person licensed under this chapter shall not engage in the practice of chiropractic as defined in RCW 18.25.005.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

WASHINGTON

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

WAC § 246-919-800

WAC 246-919-800. Purpose.

(1) The medical quality assurance commission recognizes that effective pain management is an essential component of quality medical care and that no single approach to the treatment of pain is exclusively correct.

(2) The commission wishes to reassure practitioners that they need not fear disciplinary action from the commission for prescribing, dispensing, or administering opioids when treating pain so long as the care provided is consistent with currently acceptable medical practices. This includes acute, chronic and intractable pain (RCW 69.50.308(g)).

(3) While many other medications may be appropriate in the treatment of pain, these regulations specifically address the use of opioids. As used in these regulations, the term opioid means any natural or synthetic medication that has morphine like activity.

WAC § 246-919-810

WAC 246-919-810. What specific guidance should a practitioner follow?

(1) The commission has adopted guidelines for the management of pain in order to acquaint practitioners with recognized national standards in the field of pain treatment.

(2) These guidelines specifically address the patient evaluation and treatment plan, informed consent, periodic reviews, use of consultations, and the necessity for maintaining accurate and complete medical records.

(3) These guidelines may be revised from time to time to reflect changes in the practice of pain management.

(4) Practitioners who cannot or choose not to treat patients who have complex or chronic pain conditions should offer appropriate referrals for those patients.

WAC § 246-919-820

WAC 246-919-820. What knowledge should a practitioner possess to treat pain patients?

Practitioners treating pain should be:

(1) Knowledgeable about the complex nature of pain;

(2) Familiar with the pain treatment terms used in the commission's pain treatment guidelines; and

(3) Knowledgeable about acceptable pain treatment modalities.

WAC § 246-919-830

WAC 246-919-830. How will the commission evaluate prescribing for pain?

(1) The practitioner's treatment will be evaluated by a review of the provided care to see if it is clinically sound and in accordance with currently acceptable medical practice regarding the treatment of pain.

(2) No disciplinary action will be taken against a practitioner based solely on the quantity and/or frequency of opioids prescribed.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to communicate to practitioners about acceptable practices governing pain management.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

WASHINGTON

REGULATIONS

Osteopathic Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

WAC § 246-853-510

WAC 246-853-510. Use of controlled substances for pain control.

(1) Purpose. The board of osteopathic medicine and surgery recognizes that effective pain management is an essential component of quality medical care and that no single approach to the treatment of pain is exclusively correct.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(2) The board wishes to reassure osteopathic physicians that they need not fear disciplinary action from the board for prescribing, dispensing, or administering controlled substances, including opioids, when treating pain so long as the care provided is consistent with currently acceptable osteopathic medical practices. This includes acute, chronic, and intractable pain (RCW 69.50.308(g)) patients.

WAC § 246-853-520

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to communicate to practitioners about acceptable practices governing pain management.

WAC 246-853-520. What specific guidance should an osteopathic physician follow?

The osteopathic physician should consult the Guidelines for Management of Pain approved by the board of osteopathic medicine and surgery effective September 13, 2002.

(1) The board has adopted guidelines for the management of pain in order to acquaint osteopathic physicians with recognized national standards in the field of pain treatment.

(2) These guidelines specifically address the patient evaluation and treatment plan, informed consent, periodic reviews, use of consultations, and the necessity for maintaining accurate and complete medical records.

(3) These guidelines may be revised from time to time to reflect changes in the practice of pain management.

(4) Osteopathic physicians who cannot, or choose not to, treat patients who have complex or chronic pain conditions should offer appropriate referrals for those patients.

WAC § 246-853-530

WAC 246-853-530. What knowledge should an osteopathic physician who elects to treat chronic pain patients possess?

(+) *CRITERION 4:*
Encourages pain management

Osteopathic physicians treating pain should be:

(1) Knowledgeable about the complex nature of pain;

(2) Familiar with the pain treatment terms used in the board's pain treatment guidelines; and

(3) Knowledgeable about acceptable pain treatment modalities.

WAC § 246-853-540

WAC 246-853-540. How will the board evaluate prescribing for pain?

(1) The osteopathic physician's treatment will be evaluated by a review of the provided care to see if it is clinically sound and in accordance with currently acceptable osteopathic medical practice regarding the treatment of pain.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Department of Health Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

GUIDELINES FOR MANAGEMENT OF PAIN

BACKGROUND

Substitute Senate Bill 5365 Uniform Disciplinary Act Amendments directed the Secretary of the Department of Health to "...coordinate and assist the regulatory boards and commissions of the health professions with prescribing authority in the development of uniform guidelines for addressing opiate therapy for acute pain and chronic pain associated with cancer and other terminal diseases, or other chronic or intractable pain conditions. The purpose of the guidelines is to assure the provision of effective medical treatment in accordance with recognized national standards and consistent with requirement of public health safety".

The Department of Health convened a group entitled Task Force on Policies for Management of Pain. This task force included representation from the medical, pharmacy, and nurses' associations and commissions; physicians from pain management clinics and private practice; a Washington state Representative; and patients with chronic intractable pain.

INTRODUCTION

There are widespread concerns among patients throughout the state about access to appropriate medical treatment, including opioid therapy, for addressing chronic intractable pain. Similarly, providers express apprehensions about challenges by state disciplinary authorities when prescribing opioid analgesics for indicated medical treatment when serving the legitimate medical needs of pain patients. The under treatment of chronic pain due to concerns about addiction and drug diversion affect the public health, safety and welfare. There is a need for guidance which would: a) encourage appropriate treatment for pain management; b) reduce providers' fear of injudicious discipline; and, c) protect the public from inappropriate prescribing practices and diversion.

PURPOSE STATEMENT

The Secretary of the Department of Health recommends the uniform adoption, by appropriate state regulatory authorities, of the following guidelines when managing pain. It is not the intent of these guidelines to define complete standards of acceptable medical care in the treatment of pain patients. These guidelines are not intended to direct clinical practice parameters. It is the intent that providers will have confidence that these guidelines are the standard by which opioid usage is evaluated.

POLICY STATEMENT

Under generally accepted standards of medical practice, opioids may be prescribed for the treatment of acute or chronic pain including chronic pain associated with cancer and other non-cancer pain conditions. Prescribing opioids requires special consideration. It is the position of the Department of Health that opioids may be prescribed, dispensed, or administered when there is an indicated medical need without fear of injudicious discipline.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Department of Health Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

GUIDELINES FOR OPIOID USAGE

Acute Pain

Opioids are useful for patients with acute pain such as surgery, burn, or trauma. The goal of such treatment is to provide adequate and timely pain management to the patient. Side effects of opioids that are difficult to treat may occur and must be balanced against the benefits of pain relief. The provider should, for any patient who has a history of alcoholism or other drug addictions, carefully monitor medications and when available seek appropriate consultation.

Chronic Pain Associated With Cancer

Chronic pain associated with cancer may often be successfully managed with opioids. If use of opioids is the primary analgesic strategy, adequate doses should be given frequently enough to keep the patient continuously comfortable. Addiction is rare in patients with cancer pain; tolerance and physical dependency are often unavoidable and should not interfere with opioid prescribing. Not all pain in patients with cancer is responsive to opioids; alternative strategies for managing the pain should also be made available.

Other Chronic Pain Conditions

Opioid analgesics can be useful in the treatment of patients with intractable non-cancer pain especially, where efforts to remove the cause of pain or to treat it with other modalities have failed or were not fully successful. The pain of such patients may have a number of different etiologies and may require several modalities. In addition, the extent to which pain is associated with psychological, physical, and social impairment varies greatly. Therefore, the selection for a trial of opioid therapy should be based on a careful assessment of the pain as well as the impairment experienced by the patient. Continuation of opioid therapy should be based on the provider's evaluation of the results of treatment, including the degree of pain relief, changes in psychological, physical, and social functioning, and appropriate utilization of health services. Providers are encouraged to obtain consultation from providers who are knowledgeable in pain management, particularly when managing patients with a history of alcohol abuse or previous chronic opioid use.

DEFINITIONS

1. Addiction - A disease process involving use of psychoactive substances wherein there is loss of control, compulsive use, and continued use despite adverse social, physical, psychological, or spiritual consequences.

2. Physical Dependence - A physiologic state of adaptation to a specific psychoactive substance characterized by the emergence of a withdrawal syndrome during abstinence, which may be relieved in total or in part by re-administration of the substance. Physical dependence is not necessarily associated with full blown addiction, and condition does not always equate with addiction.

3. Psychological Dependence - A subjective sense of need for a specific substance, either for its positive effects or to avoid negative effects associated with its abstinence.

4. Tolerance - State in which an increased dosage of a psychoactive substance is needed to produce a desired effect.

5. Withdrawal Syndrome - The onset of a predictable constellation of signs and symptoms following the abrupt discontinuation of, or rapid decrease in, dosage of a psychoactive substance.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Department of Health Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

6. Acute Pain - An essential biologic signal of the potential for or the extent of injury. It is usually short-lived and is associated with hyperactivity of the sympathetic nervous system; e.g. tachycardia, increased respiratory rate and blood pressure, diaphoresis, and papillary dilation. The concurrent affect is anxiety.

7. Chronic Pain - Pain persistent beyond expected healing time and often cannot be ascribed to a specific injury. Chronic pain may not have a well-defined onset and by definition does not respond to treatment directed at its causes.

8. Intractable Pain in a Non-Cancer Patient - Pain in which the cause cannot be removed or otherwise treated and no relief or cure has been found after reasonable efforts.

GUIDELINES FOR ASSESSMENT AND DOCUMENTATION IN NON-CANCER PAIN

Alternative strategies for managing pain must be explored. If alternative strategies for managing the pain are unsuccessful, long term opioid therapy can be added. The goal is not merely to treat the symptoms of pain, but to devise pain management strategies which deal effectively with all aspects of the patient's pain syndrome, including psychological, physical, social, and work-related factors. Documentation in the patient's medical record should include:

1. History and medical examination - A complete physical examination and comprehensive medical history should be part of the active treatment record including, but not limited to, a review of past pain treatment outcomes and any history of addiction risks to establish a diagnosis and treatment plan.

2. Diagnosis and medical indication - A working diagnosis must be delineated, which includes the presence of a recognized medical indication for the use of any treatment or medication.

3. Written treatment plan with recorded measurable objectives - The plan should have clearly stated, measurable objectives, indication of further planned diagnostic evaluation, and alternative treatments.

4. Informed consent - Discussions of risks and benefits should be noted in some format in the patient's record.

5. Periodic reviews and modifications indicated - At these periodic reviews, the provider should reassess the treatment plan, the patient's clinical course, and outcome goals with particular attention paid to disease progression, side effect and emergence of new conditions.

6. Consultation - The treating provider should be knowledgeable and competent in referring patients to the appropriate specialist if needed and noting in the patient's record the treating providers interpretation of the consultation reports. Additionally, a new patient with evidence of at-risk patterns of opioid usage should be evaluated by a knowledgeable specialist.

7. Records - the provider should keep accurate and complete records documenting the dates and clinical findings for all evaluations, consultations, treatments, medications and patient instructions.

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(-) *CRITERION 9:*
Opioids are a last resort

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Does this imply that opioids are a treatment of last resort?

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Department of Health Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

8. Assessment and monitoring - Some patients with chronic pain not associated with cancer may be at risk of developing increasing opioid consumption without objective improvement in functional status. Subjective reports by the patient should be supported by objective observations. Objective measures in the patient's condition are determined by an ongoing assessment of the patient's functional status, including the ability to engage in work or other gainful activities, patient consumption of health care resources, positive answers to specific questions about the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient as observed by the physician.

(+) *CRITERION 7: Physical dependence or analgesic tolerance are not confused with "addiction"*

Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy and are not the same as addiction. Addiction is a disease with behavior characterized by psychological dependence and aberrant drug related behaviors. Addicts compulsively use drugs for non-medical purposes despite harmful effects; a person who is addicted may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts, merely because they are being treated with opioids

The physician is responsible for monitoring the dosage of the opioid. Monitoring includes ongoing assessment of patient compliance with drug prescriptions and related treatment plans. Communication between health care providers is essential. The patient should receive long term analgesic medications from one physician and where possible one pharmacy. All providers should be particularly cautious with patients with a history of alcoholism or other drug addiction when prescribing long term opioids. Consults with addiction specialists are recommended.

PATIENT RESPONSIBILITIES

1. It is the patient's responsibility to candidly provide the treatment provider with a complete and accurate treatment history, including past medical records, past pain treatment and alcohol and other drug addiction history.

2. The patient should participate as fully as possible in all treatment decisions.

3. The patient and family members, if available, should inform the prescriber of all drug side effects and concerns regarding prescription drugs.

4. The patient should not use other psychoactive agents, including alcohol, naturopathic products or over-the-counter drugs without agreement of the prescriber.

5. The patient should use the same name when receiving medical care to assure completeness of the medical record.

6. The patient should demand respect and expect to be believed.

7. The patient should keep an open mind and be willing to work with the treatment provider, including:

a. negotiate with the provider to arrive at an acceptable plan of treatment;

b. be open in trying alternative treatment strategies; and

c. follow the treatment provider's instructions precisely.

8. The patient should, where possible, get all central nervous system medications from one provider. If this is not possible, the patient should inform each provider of all medication he/she is receiving.

9. The patient should, where possible, have all prescriptions filled at a single pharmacy.

10. The patient should not horde, share, or sell medications.

11. The patient should be aware that providers may, by law, share information with other providers about the patient's care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Professional Practice

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (guidelines) for the board to improve pain management.

Rev. Code Wash. (ARCW) § 18.130.340

§ 18.130.340. Opiate therapy guidelines

The secretary of health shall coordinate and assist the regulatory boards and commissions of the health professions with prescriptive authority in the development of uniform guidelines for addressing opiate therapy for acute pain, and chronic pain associated with cancer and other terminal diseases, or other chronic or intractable pain conditions. The purpose of the guidelines is to assure the provision of effective medical treatment in accordance with recognized national standards and consistent with requirements of the public health and safety.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospice Plan of Care

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospices to ensure that pain management is an essential part of patient care.

WAC § 246-335-085

WAC 246-335-085. Hospice plan of care.

(1) Hospice licensees must, except as provided in subsection (2) of this section:

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(c) Assure the hospice plan of care includes:

(i) Current diagnoses and information on health status;

(ii) Goals or outcome measures;

(iii) Symptom and pain management;

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REGULATIONS

Adult Residential Care Service

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

WAC § 388-110-220

WAC 388-110-220. Enhanced adult residential care service standards.

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(3) In a boarding home with an enhanced adult residential care-specialized dementia care services contract, for residents served under that contract, the contractor must:

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(d) Ensure that each staff who works directly with residents has at least six hours of continuing education per year related to dementia, including Alzheimer's disease. This six hours of continuing education may be part of the ten hours of continuing education required by *WAC 388-112-0205*. Appropriate topics include, but are not limited to:

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(xi) Recognizing and assessing pain in people with dementia.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (staff training) for adult residential care facilities to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

WV

WEST VIRGINIA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Chapter 60A. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Chapter 30. Professions and Occupations; Article 3. West Virginia Medical Practice Act

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Chapter 30. Professions and Occupations; Article 3A. Management of Intractable Pain

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Chapter 30. Professions and Occupations; Article 14. Osteopathic Physicians and Surgeons

- PHARMACY PRACTICE ACT
  Chapter 30. Professions and Occupations; Article 5. Pharmacists, Pharmacy Technician, Pharmacy Interns and Pharmacies

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS *(Part of Pharmacy Board Regulations)* (*No provisions found*)
  Title 15. Legislative Rule; West Virginia Board of Pharmacy; Series 2. Rules of the Board of Pharmacy for the Uniform Controlled Substances Act

- MEDICAL BOARD REGULATIONS
  Title 11. Legislative Rule; West Virginia Board of Medicine

- OSTEOPATHIC BOARD REGULATIONS
  Title 24. Legislative Rule; West Virginia Board of Osteopathy

- PHARMACY BOARD REGULATIONS
  Title 15. Legislative Rule; West Virginia Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  West Virginia Board of Medicine. *Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: January 10, 2005.

- JOINT BOARD POLICY STATEMENT
  West Virginia Examiners for Registered Professional Nurses, Medicine, Osteopathy, and Pharmacy Boards. *Joint Policy Statement on Pain Management at the End of Life*. Adopted: March 12, 2001.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- PROFESSIONAL PRACTICE

  Chapter 30. Professions and Occupations; Article 1. General Provisions Applicable to All State Boards of Examination or Registration Referred to in Chapter

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					
Medical Practice Act		●				●		
Intractable Pain Treatment Act					●			●
Osteopathic Practice Act[1]								
Pharmacy Practice Act			●					
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Osteopathic Board[1]								
Pharmacy Board			●					
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		●	●	●	●	●	●	●
Joint Board Policy Statement		●		●	●	●	●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Professional Practice								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Pain & Policy Studies Group. *Achieving Balance in Federal & State Pain Policy: A Guide to Evaluation (Fifth edition).*
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin. 2008.

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Intractable Pain Treatment Act								●
Osteopathic Practice Act[1]								
Pharmacy Practice Act[1]								
REGULATIONS								
Controlled Substances[1]								
Medical Board								●
Osteopathic Board								●
Pharmacy Board								●
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline[1]								
Joint Board Policy Statement[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Professional Practice[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

WEST VIRGINIA

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

W. Va. Code § 60A-1-101

§ 60A-1-101 Definitions

As used in this act:

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(v) "Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.

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(+) *CRITERION 3:* *Opioids are part of professional practice*

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

W. Va. Code § 30-3-4

§ 30-3-4. Definitions

As used in this article:

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(3) "Practice of medicine and surgery" means the diagnosis or treatment of, or operation or prescription for, any human disease, pain, injury, deformity or other physical or mental condition.

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(+) *CRITERION 2:* *Pain management is part of medical practice*

W. Va. Code § 30-3-14

§ 30-3-14. Professional discipline of physicians and podiatrists; reporting of information to board pertaining to professional malpractice and professional incompetence required; penalties; grounds for license denial and discipline of physicians and podiatrists; investigations; physical and mental examinations; hearings; sanctions; summary sanctions; reporting by the board; reapplication; civil and criminal immunity; voluntary limitation of license; probable cause determinations

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(c) The board may deny an application for license or other authorization to practice medicine and surgery or podiatry in this state and may discipline a physician or podiatrist licensed or otherwise lawfully practicing in this state who, after a hearing, has been adjudged by the board as unqualified due to any of the following reasons:

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(13) Prescribing, dispensing, administering, mixing or otherwise preparing a prescription drug, including any controlled substance under state or federal law, other than in good faith and in a therapeutic manner in accordance with accepted medical standards and in the course of the physician's or podiatrist's professional practice: Provided, that a physician who discharges his or her professional obligation to relieve the pain and suffering and promote the dignity and autonomy of dying patients in his or her care, and in so doing, exceeds the average dosage of a pain relieving controlled substance, in Schedule II and III of the Uniform Control Substance Act, does not violate this article;

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(+) *CRITERION 6:* *Prescription amount alone does not determine legitimacy*

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

W. Va. Code § 30-3A-1 - 30-3A-4

§ 30-3A-1. Definitions

For the purposes of this article, the words or terms defined in this section have the meanings ascribed to them. These definitions are applicable unless a different meaning clearly appears from the context.

(1) An "accepted guideline" is a care or practice guideline for pain management developed by a nationally recognized clinical or professional association, or a specialty society or government-sponsored agency that has developed practice or care guidelines based on original research or on review of existing research and expert opinion. Guidelines established primarily for purposes of coverage, payment or reimbursement do not qualify as accepted practice or care guidelines when offered to limit treatment options otherwise covered by the provisions of this article.

(2) "Board" or "licensing board" means the West Virginia board of medicine, the West Virginia board of osteopathy, the West Virginia board of registered nurses or the West Virginia board of pharmacy.

(3) "Intractable pain" means a state of pain having a cause that cannot be removed. Intractable pain exists if an effective relief or cure of the cause of the pain: (1) Is not possible; or (2) has not been found after reasonable efforts. Intractable pain may be temporary or chronic.

(4) "Nurse" means a registered nurse licensed in the state of West Virginia pursuant to the provisions of article seven [§ 30-7-1 et seq.] of this chapter.

(5) "Pain-relieving controlled substance" includes, but is not limited to, an opioid or other drug classified as a schedule II controlled substance and recognized as effective for pain relief, and excludes any drug that has no accepted medical use in the United States or lacks accepted safety for use in treatment under medical supervision, including, but not limited to, any drug classified as a schedule I controlled substance.

(6) "Pharmacist" means a registered pharmacist licensed in the state of West Virginia pursuant to the provisions of article five [§ 30-5-1 et seq.] of this chapter.

(7) "Physician" means a physician licensed in the state of West Virginia pursuant to the provisions of article three or article fourteen [§§ 30-3-1 et seq. or 30-14-1 et seq.] of this chapter.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

§ 30-3A-2. Limitation on disciplinary sanctions or criminal punishment related to management of intractable pain

(a) A physician shall not be subject to disciplinary sanctions by a licensing board or criminal punishment by the state for prescribing, administering or dispensing pain-relieving controlled substances for the purpose of alleviating or controlling intractable pain when:

(1) In a case of intractable pain involving a dying patient, the physician discharges his or her professional obligation to relieve the dying patient's intractable pain and promote the dignity and autonomy of the dying patient, even though the dosage exceeds the average dosage of a pain-relieving controlled substance; or

(2) In the case of intractable pain involving a patient who is not dying, the physician discharges his or her professional obligation to relieve the patient's intractable pain, even though the dosage exceeds the average dosage of a pain-relieving controlled substance, if the physician can demonstrate by reference to an accepted guideline that his or her practice substantially complied with that accepted guideline. Evidence of substantial compliance with an accepted guideline may be rebutted only by the testimony of a clinical expert. Evidence of noncompliance with an accepted guideline is not sufficient alone to support disciplinary or criminal action.

(b) A registered nurse shall not be subject to disciplinary sanctions by a licensing board or criminal punishment by the state for administering pain-relieving controlled substances to alleviate or control intractable pain, if administered in accordance with the orders of a licensed physician.

(c) A registered pharmacist shall not be subject to disciplinary sanctions by a licensing board or criminal punishment by the state for dispensing a prescription for a pain-relieving controlled substance to alleviate or control intractable pain, if dispensed in accordance with the orders of a licensed physician.

(d) For purposes of this section, the term "disciplinary sanctions" includes both remedial and punitive sanctions imposed on a licensee by a licensing board, arising from either formal or informal proceedings.

(e) The provisions of this section shall apply to the treatment of all patients for intractable pain, regardless of the patient's prior or current chemical dependency or addiction. The board may develop and issue policies or guidelines establishing standards and procedures for the application of this article to the care and treatment of persons who are chemically dependent or addicted.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (immunity) to protect practitioners treating intractable pain from criminal prosecution.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

§ 30-3A-3. Acts subject to discipline or prosecution

(a) Nothing in this article shall prohibit disciplinary action or criminal prosecution of a physician for:

(1) Failing to maintain complete, accurate, and current records documenting the physical examination and medical history of the patient, the basis for the clinical diagnosis of the patient, and the treatment plan for the patient;

(2) Writing a false or fictitious prescription for a controlled substance scheduled in article two [§ 60A-2-201 et seq.], chapter sixty-a of this code; or

(3) Prescribing, administering, or dispensing a controlled substance in violation of the provisions of the federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801, et seq. or chapter sixty-a of this code [§ 60A-1-101 et seq.]; or

(4) Diverting controlled substances prescribed for a patient to the physician's own personal use.

(b) Nothing in this article shall prohibit disciplinary action or criminal prosecution of a nurse or pharmacist for:

(1) Administering or dispensing a controlled substance in violation of the provisions of the federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801, et seq. or chapter sixty-a of this code [§ 60A-1-101 et seq.]; or

(2) Diverting controlled substances prescribed for a patient to the nurse's or pharmacist's own personal use.

§ 30-3A-4. Construction of article

This article may not be construed to legalize, condone, authorize or approve mercy killing or assisted suicide.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

W. Va. Code § 30-5-1b

§ 30-5-1b. Definitions

The following words and phrases, as used in this article, have the following meanings, unless the context otherwise requires:

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(31) "Practitioner" means an individual currently licensed, registered or otherwise authorized by any state, territory or district of the United States to prescribe and administer drugs in the course of professional practices, including allopathic and osteopathic physicians, dentists, physician assistants, optometrists, veterinarians, podiatrists and nurse practitioners as allowed by law.

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(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

WEST VIRGINIA

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

W. Va. Admin. Code § 11-1A-12

§ 11-1A-12, 12.1

Causes For Denial, Probation, Limitation, Discipline, Suspension, or Revocation of Licenses of Physicians and Podiatrists.

12.1 The Board may deny an application for a licensee on probation, suspend a license, limit or restrict or revoke any license heretofore or hereafter issued by the Board, upon satisfactory proof that the licensee has:

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v. Exercised influence on the patient or client in such a manner as to exploit the patient or client for the financial gain of the licensee or of a third party, which shall include, but not be limited to, the promoting or selling of services, goods, appliances or drugs and the promoting or advertising on any prescription form of a community pharmacy. For the purposes of this subdivision, it is legally presumed that prescribing, dispensing, administering, mixing or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities, is not in the best interests of the patient and is not in the course of the physician's or podiatrist's professional practice, without regard to his or her intent;

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(-) *CRITERION 16: Provisions that are ambiguous*

CATEGORY A: Arbitrary standards for legitimate prescribing

COMMENT: "Excessive" implies there is a limit, but the limit is not specified; also, eliminating the critically important intent of the physician in deciding cases appears to add to the uncertainty of how this provision might be interpreted.

REGULATIONS

Osteopathic Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

W. Va. CSR § 24-1-18

§ 24-1-18. Causes For Denial, Probation, Limitation, Discipline, Suspension Or Revocation of Licenses of Osteopathic Physicians.

18.1. The Board may deny an application for a license, place a licensee on probation, suspend a license, limit or restrict a license or revoke any license issued by the Board, upon satisfactory proof that the licensee has:

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18.1.22. Exercised influence on the patient or client in such a manner as to exploit the patient or client for the financial gain of the licensee or of a third party, which shall include, but not be limited to, the promoting or selling of services, goods, appliances or drugs and the promoting or advertising on any prescription form of a community pharmacy. For the purposes of this subdivision, it is legally presumed that prescribing, dispensing, administering, mixing or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities, is not in the best interests of the patient and is not in the course of the physician's professional practice, without regard to his or her intent;

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(-) *CRITERION 16: Provisions that are ambiguous*

CATEGORY A: Arbitrary standards for legitimate prescribing

COMMENT: "Excessive" implies there is a limit, but the limit is not specified; also, eliminating the critically important intent of the physician in deciding cases appears to add to the uncertainty of how this provision might be interpreted.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

W. Va. CSR § 15-1-2

§ 15-1-2. Definitions.

2.1. The following words and phrases as used in this Rule have the following meanings, unless the context otherwise requires:

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2.1.42. "Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which he or she practices to prescribe and administer drugs in the course of professional practices, as allowed by law.

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W. Va. CSR § 15-2-7

§ 15-2-7. Prescriptions.

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7.8. Dispensing of narcotic drugs for maintenance purposes.

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7.8.3. This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Does this imply that opioids are a last resort?

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 4:*
Encourages pain management

Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The West Virginia Board of Medicine recognizes that principles of quality medical practice dictate that the people of the State of West Virginia have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The West Virginia Board of Medicine is obligated under the laws of the State of West Virginia to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

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(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including urine/serum medication levels screening when requested; number and frequency of all prescription refills; and reasons for which drug therapy may be discontinued (e.g., violation of agreement).

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(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include the medical history and physical examination, diagnostic, therapeutic and laboratory results, evaluations and consultations, treatment objectives, discussion of risks and benefits, informed consent, treatments, medications (including date, type, dosage and quantity prescribed), instructions and agreements and periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

WEST VIRGINIA BOARDS OF EXAMINERS FOR REGISTERED NURSES, MEDICINE, OSTEOPATHY, AND PHARMACY
JOINT POLICY STATEMENT ON PAIN MANAGEMENT AT THE END OF LIFE

Rationale

The West Virginia Boards of Examiners for Registered Professional Nurses, Medicine, Osteopathy, and Pharmacy (hereinafter the Boards) recognize that:

- inadequate treatment of pain for patients at end-of-life is a serious health problem affecting thousands of patients every year;
- fear about dying in pain is the number one concern of West Virginians and all Americans facing the end of life; [1]
- principles of quality healthcare practice dictate that the people of the State of West Virginia have access to appropriate and effective pain relief; and
- the appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain at the end of life as well as reduce the morbidity associated with untreated or undertreated pain.

Insufficient pain control may result from health care professionals' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inadequate treatment of pain. **Therefore, this statement has been developed to clarify the Boards' position on adequate pain control and to address misperceptions health care professionals may have, specifically as related to the use of controlled substances for patients with terminal illness, to alleviate health care professional uncertainty and to ensure better pain management.** This statement is not intended to define complete or best practice, but rather to communicate what the Boards consider to be within the boundaries of professional practice.

It is the position of the Boards that nurses, physicians, and pharmacists (hereinafter healthcare professionals) under their respective jurisdictions shall provide adequate pain control as a part of quality practice for all patients who experience pain as a result of terminal illness. Accordingly, all health care professionals who are engaged in treating terminally ill patients are obligated to become knowledgeable about effective methods of pain assessment and treatment as well as statutory requirements for prescribing, administering, and dispensing controlled substances.

This statement applies explicitly and solely to pain management at the end of life. It creates no presumption regarding appropriate or inappropriate pain management in other circumstances.

Definitions

"Adequate pain control" means pain management that reduces a patient's moderate or severe pain to a level of mild pain or no pain at all, as reported by the patient.

"Terminal illness" means the medical condition of a patient who is dying from an incurable, irreversible disease as diagnosed by a treating physician.

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(+) *CRITERION 2:* *Pain management is part of medical practice*

(+) *CRITERION 4:* *Encourages pain management*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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Collaboration Among the Healthcare Team

Communication and collaboration among members of the healthcare team and with the patient and family are essential to achieve adequate pain control in end-of-life care. Within this interdisciplinary framework for end-of-life care, effective pain management should include at a minimum:

thorough documentation of all aspects of the patient's assessment and care;

a working diagnosis and therapeutic treatment plan including pharmacologic and non-pharmacologic interventions;

regular and documented evaluation of response to the interventions and, as appropriate, revisions to the treatment plan;

evidence of communication among care providers;

education of the patient and family; and,

a clear understanding by the patient, the family and healthcare team of the treatment goals.

Management of Pain

The management of pain should be based upon current knowledge and research and may include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly and the quantity and frequency of pain medication doses should be adjusted according to the intensity and duration of the pain. Health care professionals should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The Boards are obligated under the laws of the State of West Virginia to protect the public health and safety. The Boards recognize that inappropriate prescribing, administering, and dispensing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Health care professionals should be diligent in preventing the diversion of drugs for illegitimate purposes. While not in any way minimizing the severity of this problem, the Boards recognize that governmental policies to prevent the misuse of controlled substances should not interfere with their appropriate use for the legitimate medical purpose of providing effective relief of pain at the end of life.

Health care professionals should not fear disciplinary action from the Boards for prescribing, administering, or dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. All such prescribing must be established with clear documentation of unrelieved pain and in compliance with applicable state or federal law.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Physicians

The West Virginia Boards of Medicine and Osteopathy judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and frequency of prescribing. To facilitate communication between health care professionals, physicians should write on the prescription for a controlled substance for a terminally ill patient the diagnosis "terminal illness." The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and spiritual dimensions. The West Virginia Management of Intractable Pain Act sets forth the conditions under which physicians may prescribe opioids without fear of discipline. This act states "that in a case of intractable pain involving a dying patient, the physician discharges his or her professional obligation to relieve the dying patient's intractable pain and promote the dignity and autonomy of the dying patient, even though the dosage exceeds the average dosage of a pain-relieving controlled substance" (West Virginia Code §30-3A-1 *et seq*). This entire act is attached to this statement. Because, by law, West Virginia physicians have a professional and ethical obligation to control the pain of dying patients, the West Virginia Board of Medicine regards inadequate control of pain as a possible basis for professional discipline.[2] The West Virginia Board of Osteopathy acknowledges and accepts that osteopathic physicians have the professional and ethical obligation to control the pain of dying patients.

Nurses

The nurse is often the healthcare professional most involved in the on-going pain assessment, implementation of the prescribed pain management plan, evaluation of the patient's response to pain medications, and adjustment of the amount of medication administered based on patient status. To accomplish adequate pain control, the physician's prescription must provide dosage ranges and frequency parameters within which the nurse may titrate medication to achieve adequate pain control. Consistent with the scope of professional nursing practice (Title 19, Series 10), which includes prime consideration of comfort and safety for all patients, the registered professional nurse is accountable for implementing the pain management plan utilizing his or her knowledge and documented assessment of the patient's needs. The nurse has the authority to adjust the amount of medication administered within the dosage and frequency ranges stipulated by the treating physician and according to established protocols of the healthcare institution or agency. However, the nurse does not have the authority to change the medical pain management plan. When adequate pain control is not being achieved under the currently prescribed treatment plan, the nurse is responsible for reporting such findings to the treating physician and documenting this communication. The West Virginia Management of Intractable Pain Act sets forth the conditions under which nurses may administer opioids without fear of discipline.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Pharmacists

With regard to pharmacy practice, West Virginia has no quantity restrictions on dispensing controlled substances including those in Schedule II. This fact is significant when utilizing the federal rule and state law that allow the partial filling of Schedule II prescriptions for up to 60 days for patients who are terminally ill or in a long-term care facility. In these situations it would minimize expenses and unnecessary waste of drugs if the physician would note on the prescription that the patient is terminally ill and specify partial filling may be appropriate. The pharmacist may then dispense smaller quantities of the prescription to meet the patient's needs up to the total quantity authorized. Government-approved labeling for dosage level and frequency can be useful as guidance for patient care. Health professionals may, on occasion, determine that higher levels are justified in specific cases. Federal and state rules also allow the facsimile transmittal of an original prescription for Schedule II drugs for hospice patients. As an exception to the general rule that prescriptions for Schedule II drugs must be in writing and signed by the physician, in an emergency, a pharmacist may dispense a Schedule II pain-relieving controlled substance upon an oral prescription, provided that the quantity dispensed is limited to the amount adequate to treat the patient during the emergency, and a written prescription is supplied to the pharmacy within 7 days following the oral prescription. Pharmacy rules also allow the emergency refilling of prescriptions in Schedules III, IV, and V. The West Virginia Management of Intractable Pain Act sets forth the conditions under which pharmacists may dispense opioids without fear of discipline.

(+) ***CRITERION 8:***
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Informs practitioners about acceptable practices under Federal and state policies.

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[1] West Virginia Initiative to Improve End-of-Life Care. A Report of the Values of West Virginians and Health Care Professionals' Knowledge and Attitudes. January 2000, p. 3; Steinhauser, et al. Factors considered important at the end of life by patients families, physicians, and other care providers. JAMA 2000;284:2476-2482.

[2] American Medical Association Code of Medical Ethics. Opinions 2.20, 2.21 and 2.211.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Professional Practice

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

W. Va. Code § 30-1-7a

§ 30-1-7a Continuing education

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(1) Notwithstanding any other provision of this code or the provision of any rule to the contrary, each person issued a license to practice medicine and surgery or a license to practice podiatry or a license as a physician assistant by the West Virginia Board of Medicine, each person licensed as a pharmacist by the West Virginia Board of Pharmacy, each person licensed to practice registered professional nursing or licensed as an advanced nurse practitioner by the West Virginia Board of Examiners for Registered Professional Nurses, each person licensed as a licensed practical nurse by the West Virginia State Board of Examiners for Licensed Practical Nurses and each person licensed to practice medicine and surgery as an osteopathic physician and surgeon or certified as an osteopathic physician assistant by the West Virginia Board of Osteopathy shall complete two hours of continuing education coursework in the subject of end-of-life care including pain management during each continuing education reporting period through the reporting period ending the thirtieth day of June, two thousand five. The two hours shall be part of the total hours of continuing education required by each board by rule and not two additional hours.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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WISCONSIN

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Controlled Substances; Chapter 961. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Regulation and Licensing; Chapter 448. Medical Practices

- PHARMACY PRACTICE ACT (*No provisions found*)
  Regulation and Licensing; Chapter 450. Pharmacy Examining Board

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Controlled Substances Board

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Medical Examining Board

- PHARMACY BOARD REGULATIONS
  Pharmacy Examining Board

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  Medical Examining Board of the State of Wisconsin. *Position Statement on Pain Management*. Adopted: March 14, 2007.

- PHARMACY BOARD POLICY STATEMENT
  Wisconsin Pharmacy Examining Board. *Position Statement on the Treatment of Pain*. Adopted: December 7, 2005.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- NURSING HOMES
  Department of Health and Family Services; Chapter HFS 132. Nursing Homes; Subchapter VI. Services

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act	●	●	●					
Medical Practice Act		●						
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board			●					
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement		●	●	●	●		●	●
Pharmacy Board Policy Statement		●	●	●	●		●	●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Nursing Homes								●

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act[1]								
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement[1]								
Pharmacy Board Policy Statement[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Nursing Homes[1]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

WISCONSIN

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Wis. Stat. § 961.001

961.001. Declaration of intent.

The legislature finds that the abuse of controlled substances constitutes a serious problem for society. As a partial solution, these laws regulating controlled substances have been enacted with penalties. The legislature, recognizing a need for differentiation among those who would violate these laws makes this declaration of legislative intent:

(+) *CRITERION 1:* *Controlled substances are necessary for public health*

(1g) Many of the controlled substances included in this chapter have useful and legitimate medical and scientific purposes and are necessary to maintain the health and general welfare of the people of this state.

. . .

Wis. Stat. § 961.01

961.01. Definitions.

As used in this chapter:

. . .

(19) "Practitioner" means:

(a) A physician, advanced practice nurse, dentist, veterinarian, podiatrist, optometrist, scientific investigator or, subject to *s. 448.21 (3)* , a physician assistant, or other person licensed, registered, certified or otherwise permitted to distribute, dispense, conduct research with respect to, administer or use in teaching or chemical analysis a controlled substance in the course of professional practice or research in this state.

(+) *CRITERION 3:* *Opioids are part of professional practice*

. . .

Wis. Stat. § 961.38

961.38. Prescriptions.

(+) *CRITERION 2:* *Pain management is part of medical practice*

(1g) In this section, "medical treatment" includes dispensing or administering a narcotic drug for pain, including intractable pain.

. . .

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 2:*
Pain management is part of medical practice

Wis. Stat. § 448.01

448.01. Definitions.

In this chapter:

(2) "Disease" means any pain, injury, deformity or physical or mental illness or departure from complete health or the proper condition of the human body or any of its parts.

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(9) "Practice of medicine and surgery" means:

(a) To examine into the fact, condition or cause of human health or disease, or to treat, operate, prescribe or advise for the same, by any means or instrumentality.

(b) To apply principles or techniques of medical sciences in the diagnosis or prevention of any of the conditions described in par. (a) and in sub. (2)

(c) To penetrate, pierce or sever the tissues of a human being.

(d) To offer, undertake, attempt or do or hold oneself out in any manner as able to do any of the acts described in this subsection.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 3:*
Opioids are part of professional practice

Wis. Adm. Code Phar 8.04

Phar 8.04 Purpose of issue of prescription order.

(1) Prescription orders for controlled substances shall be issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice. Responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a prescription order within the meaning and intent of *ss. 450.01 (21)* and *961.38, Stats.* The person knowingly dispensing pursuant to such a purported order, as well as the person issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.

(2) A prescription order issued by a practitioner to obtain controlled substances for the purpose of general dispensing or administration to patients by the practitioner is not valid.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Medical Examining Board of the State of Wisconsin
Position Statement on Pain Management

The mission of The Medical Examining Board is to promote and protect the health and welfare of the citizens of the State of Wisconsin by fostering the provision of safe and competent medical care. The Board recognizes that such care involves the provision of appropriate and effective management of pain.

The under treatment of pain continues to be a significant public health problem in the United States. Inadequate pain control may result from physicians' lack of knowledge about pain assessment and management and/or their misunderstanding of the safety and efficacy of opioid analgesics, drugs that are essential for the management of moderate to severe pain. Physicians may also fear investigation or sanction by federal, state and local agencies which may lead to inappropriate treatment of pain.

The Board encourages physicians to view effective pain assessment and management as part of quality medical care for all patients with pain, whether it is acute or chronic. It is especially important for patients who are experiencing pain at the end of life. All physicians should be knowledgeable about effective methods of pain assessment and treatment as well as the statutory requirements for prescribing controlled substances. The medical management of pain should be guided by current knowledge and acceptable medical practice, which includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly and appropriately with clear documentation.

The Board recognizes that opioid analgesics are subject to abuse by individuals who seek them for mood altering and other psychological effects rather than for legitimate medical purposes. Physicians who use these drugs in the course of treatment should be diligent and incorporate established safeguards into their practices to minimize the potential for their diversion and abuse.

The Board further recognizes that tolerance and physical dependence are normal consequences of the sustained use of opioid analgesics and are not synonymous with psychological dependence (addiction). Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial and environmental factors influencing its development and manifestations. It is characterized by behaviors that include: impaired control over drug use, craving, compulsive use, and continued use despite harm. Persons with a history of drug abuse have the right to appropriate pain management, even if opioids must be used. Such persons may require specialized care. Tolerance may occur but it is not an inevitable consequence of chronic opioid therapy. Physical dependence is a normal and predictable state of adaptation to a drug, and by itself, does not equate with addiction.

Physicians should not fear disciplinary action from the Board for administering controlled substances, including opioid analgesics, for a legitimate medical purpose in the usual course of professional practice. The Board will initially consider the use of controlled substances for the treatment of pain to be for a legitimate medical purpose based on accepted scientific knowledge of the treatment of pain, patient clinical presentation and sound clinical judgment. Proper written documentation, the patient's medical condition and clinical response to treatment provide strong foundations for verifying optimal patient care, if review of the patient record is necessitated at some future time.

The Medical Examining Board of the State of Wisconsin is adopting and disseminating this position statement to support and encourage safe, competent, and high quality medical care for persons with pain. By so doing, the Board clearly communicates to physicians that it:

1) encourages safe and effective pain management practices
2) recognizes that pain management, which may involve the use of opioid analgesics, is a critical part of medical practice
3) will not sanction physicians solely for providing opioid analgesics provided the physician administers the medication in a safe and effective manner in compliance with state and federal law.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Comment: Identifies numerous important barriers to access to appropriate pain relief.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not contraindicate appropriate pain management.

(+) *CRITERION 3:*
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Pharmacy Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

The Wisconsin Pharmacy Examining Board Examining Board encourages patient pain control by optimizing the Patient - Pharmacy – Medical care management triad.

BACKGROUND

The Wisconsin Pharmacy Examining Board has been approached by June L. Dahl, PhD, Director of the Wisconsin Pain Initiative and Matt Bromley, Communications and Policy Director for the American Alliance of Cancer Pain Initiatives, to expand its position statement of *Pain & Policy Studies Group on Wisconsin Pharmacists and Schedule II Medications* as published in the Board's Wisconsin Regulatory Digest article *Volume 13, No. 2 October, 2001* http://drl.wi.gov/boards/phm/digest/20011000.pdf

A survey of Wisconsin pharmacists' knowledge and attitudes about dispensing opioid analgesics for chronic cancer and non-cancer pain was published in the March/April 2001 issue of the Journal of the American Pharmaceutical Association. http://www.medsch.wisc.edu/painpolicy/publicat/01japhak/01japhak.htm The study found that not all pharmacists knew what constituted legitimate dispensing practices for controlled substances under federal or state policy in emergencies or for patients with terminal illness. Also many pharmacists were unaware of the distinction between addiction, physical dependence, and tolerance. The Board encourages pharmacists to re-educate themselves with current literature on pain management. Appropriate pain control can improve or at least maintain a patient's quality of life. It is the pharmacist's duty to provide medications along with proper counseling to ensure pain control. The PEB considers refusal to fill a Schedule II prescription based on speculation or ignorance unacceptable.

Specifically, this expanded Position Board Statement clearly articulates to pharmacists that the Board;
1) encourages pain management;
2) recognizes that pain management, and the use of opioids for pain management, are a part of medical / pharmacy practice; and,
3) recognizes confusion exists around the terms addiction, physical dependence and tolerance.

While developing this statement, the Board surveyed multiple other state's Position Statements for completeness and consistency. The Board acknowledges utilization of the position statements of The Iowa and Texas Boards of Pharmacy.

As with all professional and practice questions, should they require clarification, the Board encourages Pharmacist contact. Written correspondence is preferred either via the Department of Regulation and Licensing URLs or by US Postal Service.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Pharmacy Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

The Wisconsin Pharmacy Examining Board
Position Statement on the Treatment of Pain

The mission of The Wisconsin Pharmacy Examining Board is to promote, preserve and protect the public health, safety and welfare by fostering provision of quality pharmaceutical care to all Wisconsinites. The Board recognizes quality care dictates the citizens of the State of Wisconsin have access to appropriate and effective pain relief. The appropriate application of current knowledge, practice standards and treatment modalities can serve to improve the quality of life for those patients who suffer from pain. This in turn will reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages pharmacists to view effective pain management as a part of quality care for ALL patients with pain, acute or chronic. It is especially important for patients who experience pain as a result of terminal illness. All pharmacists should become knowledgeable about effective methods of pain treatment, as well as, statutory requirements for dispensing controlled substances.

Inadequate pain control may result from physicians' and pharmacists' lack of knowledge about pain management or an inadequate understanding of addiction. The Board recognizes controlled substances, including opioid analgesics, may be essential in the treatment of pain, whether acute due to trauma or surgery or chronic due to cancer or non-cancer origins.

The Board recognizes controlled substances are subject to abuse by individuals who seek them for mood altering and other psychological effects rather than their legitimate medical uses. When dispensing controlled substances, the pharmacist should be diligent in preventing them from being diverted from legitimate to illegitimate use.

Tolerance and physical dependence are normal consequences of sustained use of these drugs and are NOT synonymous with psychological dependency (addiction). Psychological dependency is characterized by the compulsion to take a drug despite its harmful and destructive effect on the individual. Tolerance represents a secondary medical condition requiring pharmacy and medical assistance to resolve and continue patient pain control. Psychological dependency requires social (regulatory), plus pharmacy and medical assistance to maximize patient care while controlling the harmful and destructive patient behavior.

As with all medication therapies, the Board affirms the pharmacist's duty to provide medications along with proper counseling to ensure pain control. Failure to:

a) counsel, monitor and assist the patient in receiving optimal care of any condition or, b) knowingly facilitating care, continuing care or providing medications known to be inappropriate to the patient is unprofessional practice with the possibility of discipline under various Board rules plus Wisconsin and Federal Regulations. IE, controlled substances shall only be dispensed for legitimate medical purposes.

By participating as a member of the health care team, Pharmacists should NOT fear disciplinary action from the Board for dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose in the usual course of professional practice. The Board will initially consider dispensing controlled substances for pain to be for a legitimate medical purpose based on accepted scientific knowledge of the treatment of pain, patient clinical presentation and sound clinical judgment. All such dispensing must be based on clear documentation in the patient's pharmacy records of the patient's medical condition plus pertinent discussions with the prescribing practitioner. Using proper written documentation, the patient's medical condition and clinical response to treatment provide a strong foundation for verifying optimal patient care, if review of the patient record is necessitated at some future time.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Nursing Homes

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for nursing homes to ensure that pain management is an essential part of patient care.

Wis. Adm. Code HFS 132.60

HFS 132.60 Resident care.

(1) INDIVIDUAL CARE. Unless it is in conflict with the plan of care, each resident shall receive care based upon individual needs.

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(c) Basic nursing care. 1. Nursing care initiated in the hospital shall be continued immediately upon admission to the nursing home unless ordered otherwise by the admitting physician.

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5. The nursing home shall provide appropriate assessment and treatment of pain for each resident suspected of or experiencing pain based on accepted standards of practice that includes all of the following:

a. An initial assessment of pain intensity that shall include: the resident's self-report of pain, unless the resident is unable to communicate; quality and characteristics of the pain, including the onset, duration and location of pain; what measures increase or decrease the pain; the resident's pain relief goal; and the effect of the pain on the resident's daily life and functioning.

b. Regular and periodic reassessment of the pain after the initial assessment, including quarterly reviews, whenever the resident's medical condition changes, and at any time pain is suspected, including prompt reassessment when a change in pain is self-reported, suspected or observed.

c. The delivery and evaluation of pain treatment interventions to assist the resident to be as free of pain as possible.

d. Consideration and implementation, as appropriate, of non-pharmacological interventions to control pain.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

WYOMING

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 35. Public Health and Safety; Chapter 7. Food and Drugs; Article 10. Controlled Substances

- MEDICAL PRACTICE ACT
  Title 33. Professions and Occupations; Chapter 26. Physicians and Surgeons

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 33. Professions and Occupations; Chapter 24. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Agency 024. Commerce Department; Sub-Agency 060. Commissioner of Drugs and Substances Control; Rules and Regulations

- MEDICAL BOARD REGULATIONS
  Agency 024. Commerce Department; Sub-Agency 052. Board of Medicine Rules and Regulations

- PHARMACY BOARD REGULATIONS
  Agency 024. Commerce Department; Sub-Agency 059. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  Wyoming Board of Medicine. *Memo to All Wyoming Physicians and Physician Assistants*. Adopted: December 15, 2005.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

No policies found

WY

Provisions that may *ENHANCE* pain management

Criteria	1 Controlled substances are necessary for public health	2 Pain management is part of medical practice	3 Opioids are part of professional practice	4 Encourages pain management	5 Addresses fear of regulatory scrutiny	6 Prescription amount alone does not determine legitimacy	7 Physical dependence or analgesic tolerance are not confused with "addiction"	8 Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			●					●
Medical Practice Act		●						
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances[1]								
Medical Board		●						
Pharmacy Board			●					
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement								●
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES[2]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act[1]								
Medical Practice Act				●				
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act[2]								
REGULATIONS								
Controlled Substances			●					
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement[1]								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES[2]								

Note: A dot indicates that one or more provisions were identified
[1] No provisions were found in this policy, [2] No policy found

WYOMING

STATUTES

Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Wyo. Stat. § 35-7-1002

§ 35-7-1002 Definitions

(a) As used in this act:

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(xx) "Practitioner" means:

(A) A physician, dentist, veterinarian, podiatrist, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research in this state;

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(+) *CRITERION 3:*
Opioids are part of professional practice

Wyo. Stat. § 35-7-1060

§ 35-7-1060 Controlled substances prescription tracking program

(a) In addition to other duties and responsibilities as provided by this act, the board shall maintain a computerized program to track prescriptions for controlled substances for the purposes of assisting patients, practitioners and pharmacists to avoid inappropriate use of controlled substances and of assisting with the identification of illegal activity related to the dispensing of controlled substances. The tracking program and any data created thereby shall be administered by the board, and the board may charge reasonable fees to help defray the costs of operating the program. Any fee shall be included with and in addition to other registration fees established by the board as authorized in W.S. 35-7-1023.

(b) All prescriptions for schedule II, III and IV controlled substances dispensed by any retail pharmacy licensed by the board shall be filed with the board electronically or by other means required by the board. The board may require the filing of other prescriptions and may specify the manner in which the prescriptions are filed.

(c) The tracking program shall not be used to infringe on the legal use of a controlled substance. Information obtained through the controlled substance prescription tracking program is confidential and may not be released and is not admissible in any judicial or administrative proceeding, except as follows:

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that a prescription monitoring program should not interfere with the legitimate medical use of controlled substances.

Wyo. Stat. § 35-25-203

§ 35-25-203. Cancer control plan and program.

(a) The department shall develop a comprehensive cancer control plan.

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(iv) Palliative care including pain management and other steps to improve the quality of life of probably terminal cancer patients;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (cancer control plan and program) to ensure that pain management is an essential part of patient care.

Wyo. Stat. § 35-25-206

§ 35-25-206. Pain management.

(a) The department may establish an acute and chronic pain management advisory committee consisting of the following members:

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (pain management advisory committee) to provide practitioners information/education about pain management and palliative care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

WYOMING

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Wyo. Stat. § 33-26-102

§ 33-26-102 Definitions

(a) As used in this chapter:

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(xi) "Practicing medicine" means any person who in any manner:

(A) Advertises, holds out, or represents to the public that he is authorized to practice medicine in this state; or

(B) Offers or undertakes to prevent, diagnose, correct or treat, in any manner, by any means, method or device, any human disease, illness, pain, wound, fracture, infirmity, defect or abnormal physical or mental condition, injury, deformity or ailment, including the management of pregnancy and parturition;

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Wyo. Stat. § 33-26-402

§ 33-26-402 Grounds for suspension; revocation; restriction; imposition of conditions; refusal to renew or other disciplinary action

(a) The board may refuse to renew, and may revoke, suspend or restrict a license or take other disciplinary action, including the imposition of conditions or restrictions upon a license on one (1) or more of the following grounds:

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(xi) Except as permitted by law, repeatedly prescribing or administering, selling or supplying any drug legally classified as a narcotic, addicting or scheduled drug to a known abuser;

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(+) *CRITERION 2:*
Pain management is part of medical practice

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

COMMENT: Wyoming law does not seem to create an exemption for patients with pain and a history of addiction.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

WYOMING

REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

WCWR 024-060-001

Section 1.01. Definitions.

As used herein, the following terms shall have the meanings specified:

(f) The term "Drug Dependent Person" means a person who is using a controlled substance and who is in a state of psychic or physical dependence, or both arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.

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REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

WCWR 024-052-001

Chapter 1 LICENSE ELIGIBILITY, APPLICATION AND INTERVIEWS

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Section 3. Definitions.

The definitions contained in W.S. 33-26-102 and those contained in the APA are incorporated herein by this reference. In addition, the following definitions apply to this chapter:

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(k) "Practicing medicine" means any person who in any manner:

(i) Advertises, holds out or represents to the public that he is authorized to practice medicine in this state; or

(ii) Offers or undertakes to prevent, diagnose, correct or treat, in any manner, by any means, method or device any human disease, illness, pain, wound, fracture, infirmity, defect or abnormal physical or mental condition, injury, deformity or ailment, including the management of pregnancy and parturition;

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(+) *CRITERION 2:*
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

WYOMING

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

WCWR 024-059-002

CHAPTER 002. GENERAL PRACTICE OF PHARMACY REGULATIONS

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Section 4. Definitions.

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(w) "Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which he/she practices to prescribe drugs in the course of professional practice.

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(+) *CRITERION 3: Opioids are part of professional practice*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Wyoming Board of Medicine

MEMO TO: **ALL WYOMING PHYSICIANS And PHYSICIAN ASSISTANTS**

From: John H. Babson, President
Wyoming Board of Medicine

Re: ***Medical charts for patients Using Schedule II-IV controlled drugs***

Date: December 15, 2005

Many physicians worry about how to care for patients with intractable pain: Should addiction be feared more than pain relief? Will adequate pain relief lead to trouble with the Board of Medicine? What resources are available to help me with patients taking medicine for chronic pain: have I consulted the **Wyoming Board of Pharmacy's Prescription Drug Monitoring Program (**PDMP)?

Though the first question will remain a matter of professional judgment, the second can be easily answered: **The Board of Medicine has NEVER SANCTIONED A PHYSICIAN FOR PAIN MANAGEMENT THAT IS APPROPRIATE AND WELL DOCUMENTED.**

The Board has investigated cases involving extraordinary amounts of controlled substances. In most instances, the physicians involved presented an adequate diagnostic basis for the therapy and produced extensive, detailed documentation in support of the decisions. The investigations in those matters were closed without disciplinary action. In a few situations, however, physicians were unable to produce sufficient documentation and they faced different results, generally Board mandated courses in pain management and/or record maintenance.

To assure yourself that your documentation is appropriate, please consider the following:

5. Be sure that your medical records contain evidence of an **ADEQUATE HISTORY AND PHYSICAL,** including an assessment of pain and physical and psychological function. Always include a notation indicating inquiry into substance abuse history, and assessment of underlying and coexisting disease and a review of any recognized medical indication for controlled substances. Document attempts to maintain the patient on the lowest dose necessary to achieve relief and improve function;
6. **YOUR TREATMENT PLAN SHOULD DISCLOSE CLEAR CUT, OBJECTIVE CRITERIA** by which the patient's progress can be measured. Though physicians should tailor pain relief to each patient's individual needs, goals such as pain relief and improved physical and psychosocial function should be included and progress carefully monitored and noted;
7. Make certain that your records indicate that you **DISCUSSED THE RISKS AND BENEFITS WITH THE PATIENT,** reviewed other, available treatment options and noted the patient's understanding and consent in the chart;
8. Your records must reflect **PERIODIC REVIEW OF THE TREATMENT COURSE.** New information should be added to the records along with appropriate assessment of continued treatment and the trial of other modalities;

(CONTINUED ON NEXT PAGE)

(+) ***CRITERION 8:***
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

9. **DOCUMENT CONSULTATIONS WITH OTHER PHYSICIANS AND HEALTH CARE PROVIDERS.** Consult with colleagues knowledgeable and experienced in handling prolonged treatment with controlled substances. The chart should also reflect your willingness to refer the patient for evaluation and treatment to achieve the goals of the treatment plan. If you or the patient has any qualms about a proposed treatment plan, suggest a second opinion. Physicians should pay special attention and document any indication that their patient is at risk of misuse, diversion and/or past or potential substance abuse disorder;
10. To the extent possible, assure yourself that the **RECORDS INDICATE ALL MEDICATIONS THE PATIENT IS TAKING,** the purpose for each medication, the duration, dose and frequency and identification of the physician, PA or APN writing the prescriptions;
11. Ask the patient and document inquiries about obtaining **CONTROLLED SUBSTANCES FROM OTHER SOURCES,** including physicians, the internet and any other provider;
12. Be certain that your **ACTIONS ARE IN COMPLIANCE WITH FEDERAL AND STATE SUBSTANCE ABUSE LAWS AND REGULATIONS.** Call the **Wyoming Board of Pharmacy** if you have any questions about prescribing: **307-234-0294**
13. Please be sure the entire chart, including hospital records, is **LEGIBLE.** Documentation, no matter how complete, is of little value if it cannot be read.

PRESCRIPTION DRUG MONITORING PROGRAM

In addition to careful planning and adequate chart notation, the Wyoming Board of Pharmacy has developed a tool to assist you in patient care. **THE PRESCRIPTION DRUG MONITORING PROGRAM (PDMP), IS A DATA BASE COLLECTING MONTHLY REPORTS OF PATIENT SPECIFIC DATA FROM ALL WYOMONG PHARMACIES FOR ALL SCHEDULE II, III AND IV CONTROLLED SUBSTANCE PRESCRIPTIONS DISPENSED TO WYOMING RESIDENTS.**

Accessible to all licensed providers holding a valid unrestricted DEA number, you can request a specific patient profile for all or selected scheduled drugs over a defined time period. Upon a faxed request from a physician the Pharmacy Board will generate the requested report within one hour. Additionally, the Pharmacy Board frequently generates unsolicited patient profiles and mails them to practitioners who prescribed, and the pharmacies that dispensed the drugs in question.

If interested in using this valuable service, please utilize a personalized profile request (PPR) sent to you with your DEA number. You can obtain PPR forms by contacting Denise Embury, Records Analyst at the Board of Pharmacy, 307-234-0294.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

SECTION IX:
Example Language to Improve Pain-Related Policy

Purpose of this section

Policy affecting pain management can be improved by repealing or amending negative provisions and by adopting new positive provisions. This section presents examples of provisions from pain policies, including from federal law, expert bodies, and the states. Model or uniform acts are referenced where applicable; they are the product of careful consideration and drafting by expert bodies. Although not an exhaustive compilation, this section provides language that can be adopted or adapted as alternatives to existing statutes, regulations, or guidelines according to the policy needs of individual states.

Using this section

The need to consider using provisions in this section will become apparent after reviewing how the policies of a particular state have been evaluated, which is presented in the State Profiles section (see Section VIII). Improving balance means increasing the provisions with potential to enhance pain management, and decreasing those that may impede it. If a state has few positive provisions, Part A can be used to identify provisions to consider adopting. If a state has a number of negative provisions, Part B can provide guidance for repealing the language or adopting alternatives. Example language is not given for Criterion #8, Criterion #15, or Criterion #16 because these criteria can be applied to a number of diverse issues; the policy language associated with these criteria can be found for each state in the State Profiles section (Section VIII).

It is important to note that this is not a comprehensive overview of the ways that states can improve patient access to adequate pain management through policy adoption or change. The criteria used to evaluate state pain policies directly relate to the Central Principle of Balance, and affect the availability and medical use of opioid analgesics. Some states, however, have developed legislative or regulatory policies that have the potential to impact pain management, but which do not contain language that fulfills the evaluation criteria. Although such policy may ultimately have beneficial consequences for patients' pain relief, they contain no language associated with any of the evaluation criteria; therefore, neither positive nor negative provisions are identified. Consequently, a policy can contribute to pain management but fail to contain language that meets the evaluation criteria.

Pointers

Model Policy. Evaluation of the Federation's *Model Policy*, using the criteria in this publication, shows that it satisfies most positive criteria and contains no negative provisions. Adoption of the *Model Policy* by state professional licensing boards will enhance the evaluation of a state's pain policies. Consequently, state healthcare regulatory boards are encouraged to adopt new policies, or amend their existing guidelines, according to the recent national standard created by the Federation. To date, 32 states have adopted the *Model Policy*, or the previous *Model Guidelines*, either whole or in part.

Legislation. In general, legislation involving the use of controlled substances in pain management and medical practice should be avoided because of the unpredictability of the legislative process and the risk of undue regulation of medical practice and decisions about patient care. However, if impediments exist in statute, only the legislative process can remove

them. Depending on their significance, specific legislation may be needed, or may be delayed until there is an opportunity to rectify the problem as an amendment to other legislation.

Cautions. The purpose of this document is to promote positive policy change, ultimately leading to more balanced policy regarding the use of controlled substances for pain management. Positive policy change, however, is not enough. To be effective, policy adoption must be followed by consistent implementation and efforts to communicate the policy widely and repeatedly to healthcare professionals to encourage positive practice change.

The model provisions are presented in the same order as the evaluation criteria. Many of the specific provisions are taken from models, which can be adopted in their entirety.

PART A. Provisions That May Enhance Pain Management

The following provisions may be considered for inclusion in policies that currently lack language to enhance pain management.

CRITERION #1. CONTROLLED SUBSTANCES ARE RECOGNIZED AS NECESSARY FOR THE PUBLIC HEALTH

The following are examples of provisions expressing that controlled substances are necessary for the public health. Without such a provision, a state's controlled substances law would focus disproportionately on the abuse potential of opioids, thereby creating an unbalanced policy. Such a provision is present in international narcotics control treaties, and the federal CSA, and should be present in a state's Controlled Substances Act.

FEDERAL CONTROLLED SUBSTANCES ACT

"Many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." *(21 USCS §801(1))*

UNIFORM CONTROLLED SUBSTANCES ACT

"Legitimate use of controlled substances is essential for public health and safety, and the availability of these substances must be assured." *(National Conference of Commissioners on Uniform State Laws, 1994)*

WISCONSIN - STATUTE - Uniform Controlled Substances Act

"Many of the controlled substances included in this chapter have useful and legitimate medical and scientific purposes and are necessary to maintain the health and general welfare of the people of this state." *(Wis. Stat. § 961.001 (1g))*

Note: Adopted from the Federal Controlled Substances Act (21 USCS §801(1)).

CRITERION #2. PAIN MANAGEMENT IS RECOGNIZED AS PART OF GENERAL MEDICAL PRACTICE

The following language clearly recognizes that pain management is a part of medical practice. This language follows the Federation's well-established model Modern Medical Practice Act (MMPA) and should appear in a state's Medical Practice Act or regulations, and also has been adopted into the practice acts of other healthcare professions.

MODERN MEDICAL PRACTICE ACT

Definitions.
"The definition of the practice of medicine should include…offering or undertaking to prevent or to diagnose, correct and/or treat in any manner or by any means, methods, or devices any disease, illness, pain, wound, fracture, infirmity, defect or abnormal physical or mental condition of any person, including the management of pregnancy and parturition." *(Federation of State Medical Boards of the U.S., 2000)*

COLORADO – STATUTE – Controlled Substances Act

"(1) As used in this section, 'medical treatment' includes dispensing or administering a narcotic drug for pain, including intractable pain." *(CO Rev. Stat. CSA 18-18-308)*

RHODE ISLAND – STATUTE – Medical Practice Act

Definitions.
"'The practice of medicine' shall include the practice of allopathic and osteopathic medicine. Any person shall be regarded as practicing medicine within the meaning of this chapter who holds himself or herself out as being able to diagnose, treat, operate, or prescribe for any person ill or alleged to be ill with disease, pain, injury, deformity or abnormal physical or mental condition, or who shall either profess to heal, offer or undertake, by any means or method to diagnose, treat, operate, or prescribe for any person for disease, pain, injury, deformity or physical or mental condition." *(R.I. Gen. Laws 5-37-1 (13))*

Note: Adopted from the Modern Medical Practice Act (Federation of State Medical Boards, 1988)

NEW JERSEY – STATUTE – Osteopathic Practice Act

"…the practice of osteopathy shall include the diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity, mental or physical condition." *(N.J. Stat. §45:9-14.3)*

Note: Adopted from the Modern Medical Practice Act (Federation of State Medical Boards, 1988)

IOWA – REGULATION – Medical Board Regulations

Definitions.
"'The practice of medicine and surgery' shall mean holding one's self out as being able to diagnose, treat, operate or prescribe for any human disease, pain, injury, deformity or physical or mental condition and who shall either offer or undertake, by any means or methods, to diagnose, treat, operate or prescribe for any human disease, pain, injury, deformity or physical or mental condition." *(653 IAC 10.1(17A,147))*

Note: Adopted from the Modern Medical Practice Act (Federation of State Medical Boards, 1988)

TENNESSEE – REGULATION – Osteopathic Board Regulations

"The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness." *(1050-2-.13)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

FLORIDA – REGULATION – Pharmacy Board Regulations

"The Board encourages pharmacies to view pain management as a part of quality pharmacy practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness." *(64B16-27.831, F.A.C.)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

CONNECTICUT – Medical Board Guideline

"...the Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness." *("Statement of the Connecticut Medical Examining Board on the Use of Controlled Substances for the Treatment of Pain." Pennsylvania State Board of Medicine Bulletin. pp. 4-5. Winter 1998-1999. Effective: October 20, 1998)*

Note: Adopted from the Model Policy for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 2004)

WISCONSIN – Pharmacy Board Policy Statement

"The Board encourages pharmacists to view effective pain management as a part of quality care for all patients with pain, acute or chronic." *(Wisconsin Pharmacy Examining Board. "Position Statement on the Treatment of Pain." Effective: December 7, 2005)*

WEST VIRGINIA – Joint Board Policy Statement

"The West Virginia Boards of Examiners for Registered Professional Nurses, Medicine, Osteopathy, and Pharmacy (hereinafter the Boards) recognize that…principles of quality healthcare practice dictate that the people of the state of West Virginia have access to appropriate and effective pain relief." *(West Virginia Examiners for Registered Professional Nurses, Medicine, Osteopathy, and Pharmacy Boards. "Joint Policy Statement on Pain Management at the End of Life." Adopted March 12, 2001)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

CRITERION #3. MEDICAL USE OF OPIOIDS IS RECOGNIZED AS LEGITIMATE PROFESSIONAL PRACTICE

This language recognizes that the use of opioids as controlled substances is a legitimate, and therefore legal, medical practice. Sometimes the medical use of opioids has been relegated to the periphery of practice or even outside practice. Such recognition is an important contribution to a balanced regulatory environment for physicians, osteopaths, pharmacists, and nurses.

NEW YORK – STATUTE – Controlled Substances Act

"'Practitioner' means: A physician, dentist, podiatrist, veterinarian, scientific investigator, or other person licensed, or otherwise permitted to dispense, administer or conduct research with respect to a controlled substance in the course of a licensed professional practice…" *(NY CLS Pub Health §3302)*

MICHIGAN – STATUTE – Medical Practice Act

"(1) The legislature finds that the use of controlled substances is appropriate in the medical treatment of certain forms of intractable pain, and that the efforts to control diversion or improper administration of controlled substances should not interfere with the legitimate, medically recognized use of those controlled substances to relieve pain and suffering." *(MPA 14.15 (16204c))*

NEW JERSEY – STATUTE – Pharmacy Practice Act

"'Practitioner' means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which the individual practices to administer or prescribe drugs in the course of professional practice." *(N.J. Stat. §45:14-41)*

ARKANSAS – REGULATION – Controlled Substances Regulations

"A physician, podiatric physician, osteopathic physician, dentist, veterinarian, optometrist, scientific investigator, researcher, mid-level practitioner, or other persons licensed, registered, or otherwise permitted to prescribe, dispense, distribute, administer or conduct research with respect to controlled substances in the course of professional practice." *(007 07 CARR 009)*

UTAH – REGULATION – Professional Practice Regulations

"The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment." *(R156-1-502)*

Note: Adopted from the Model Policy for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 2004)

ALABAMA – REGULATION – Medical Board Regulations

"The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds." *(540-X-4-.08 AAC)*

Note: Adopted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

TENNESSEE – REGULATION – Osteopathic Board Regulations

"The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds." *(1050-2-.13)*

Note: Adopted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

IDAHO – REGULATION – Pharmacy Board Regulations

" 02. Individual Practitioner. The term 'individual practitioner' means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the state in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner." *(IDAPA 27.01.01.433)*

SOUTH DAKOTA – Medical Board Guideline

"The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment..." *(South Dakota State Board of Medical and Osteopathic Examiners. "The Federation of State Medical Boards of the United States, Inc. Model Guidelines for the Use of Controlled Substances for the Treatment of Pain." Effective: January, 1999)*

Note: Adopted from the Model Policy for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 2004)

ARIZONA – Osteopathic Board Guideline

"The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds." *(Arizona Board of Osteopathic Examiners in Medicine and Surgery Guidelines. "The Prescribing of Controlled Substances for the Treatment of Pain Management." Effective: January 22, 2000)*

Note: Adopted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

IOWA – Pharmacy Board Policy Statement

"The Board recognizes that the use of controlled substances, including opioid analgesics, is often essential for adequate pain control." *(Iowa Board of Pharmacy Examiners. "The Treatment of Pain." Effective: February 12, 2002)*

KANSAS – Joint Board Policy Statement

"Prescribing, administering or dispensing controlled substances, including opioid analgesics, to treat pain is considered a legitimate medical purpose if based upon sound clinical grounds. *(Kansas State Boards of Healing Arts, Nursing, and Pharmacy*." *"Joint Policy Statement by the Boards of Healing Arts, Nursing, and Pharmacy on the Use of Controlled Substances for the Treatment of Pain." Approved: July 17, 2002)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

CRITERION #4. PAIN MANAGEMENT IS ENCOURAGED

Is it the policy of the state to encourage pain management? Although some states have taken steps to improve pain management, the answer to this important question can be made explicitly clear by including specific language in state policy. Several states have adopted policies that encourage pain management. Such language can occur in statutes, regulations, or guidelines – an appropriate place to add such language would be in state board policies that regulate the health professions and establish standards of practice.

OKLAHOMA – STATUTE – Uniform Controlled Substances Act

"The State of Oklahoma encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic. It is especially important for patients who experience pain as a result of terminal illness." *(63 Okl. St. § 2-551)*

ARKANSAS – STATUTE – Medical Practice Act

"The General Assembly finds that: (1) Pain management plays an important role in good medical practice." *(ACA§ 17-95-701-707)*

NEBRASKA – STATUTE – Public Health and Welfare

"The Legislature therefore encourages physicians to view effective pain management as part of quality medical practice for all patients with pain, acute or chronic, including those patients who experience pain as a result of terminal illness." *(Pub Health and Welfare 71-2418)*

UTAH – REGULATIONS – Professional Practice Regulations

"Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management." *(R156-1-502)*

Note: Adopted from the Model Policy for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 2004)

IOWA – REGULATIONS – Medical Board Regulations

"The purpose of the rule is to assist physicians who prescribe and administer drugs to provide relief and eliminate suffering in patients with chronic, nonmalignant pain as defined in this rule." *(635 IAC 10.1(17A,147))*

TENNESSEE – REGULATIONS – Osteopathic Board Regulations

"Accordingly, these guidelines have been developed to... encourage better pain management." *(1050-2-.13)*

Note: Adopted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

FLORIDA – REGULATIONS – Pharmacy Board Regulations

"Accordingly, these guidelines have been developed to...encourage pain management." *(64B16-27.831, F.A.C.)*

Note: Adopted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

CALIFORNIA – Medical Board Guideline

"These Guidelines are intended to promote improved pain management for all forms of pain and for all patients in pain." (California Medical Board. "Guideline for Prescribing Controlled Substances for Intractable Pain." *Action Report*. Vol. 87, pp. 1, 4-6. October 2003. Adopted: August 2, 2003)

ARIZONA – Osteopathic Board Guideline

"The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of a terminal illness." *(Arizona Board of Osteopathic Examiners in Medicine and Surgery Guidelines. "The Prescribing of Controlled Substances for the Treatment of Pain Management." Effective: January 22, 2000)*

Note: Adopted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

MICHIGAN – Pharmacy Board Guideline

"The Board encourages pharmacists to view effective pain management as a part of quality health care for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness." (Michigan Board of Pharmacy. "*Michigan Board of Pharmacy Guidelines for the Use of Controlled Substances for the Treatment of Pain.")*

Note: Adopted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

KANSAS – Joint Board Policy Statement

"The boards adopt this statement to help assure health care providers and patients and their families that it is the policy of this state to encourage competent comprehensive care for the treatment of pain." *(Kansas Boards of Healing Arts, Nursing, and Pharmacy "Joint Policy Statement of the Boards of Healing Arts, Nursing, and Pharmacy on the Use of Controlled Substances for the Treatment of Pain." Effective: 7/17/2002)*

CRITERION #5. PRACTITIONERS' CONCERNS ABOUT REGULATORY SCRUTINY ARE ADDRESSED

Fear of regulatory scrutiny, real or perceived, is an important impediment to the adequate management of pain and should be addressed to achieve a balanced regulatory environment. A number of states have adopted provisions in statutes, regulations, and guidelines to allay these fears. It should be noted that adoption of policy alone may have little effect until it is implemented and observed by government agencies, as well as understood and accepted by practitioners. Adoption of such a policy should be preceded by a review of enforcement, regulatory, or disciplinary actions and media coverage so that the agency adopting the policy is prepared to address the reasons for concerns in any meetings or materials that accompany the policy.

NEW MEXICO – STATUTE – Pain Relief Act

"No health care provider who prescribes, dispenses or administers medical treatment for the purpose of relieving intractable pain and who can demonstrate by reference to an accepted guideline that his practice substantially complies with that guideline and with the standards of practice identified in Section 4 of the Pain Relief Act shall be subject to disciplinary action or criminal prosecution, unless the showing of substantial compliance with an accepted guideline is rebutted by clinical expert testimony. If no currently accepted guidelines are available, then rules issued by the board may serve the function of such guidelines for purposes of the Pain Relief Act. The board rules must conform to the intent of that act. Guidelines established primarily for purposes of coverage, payment or reimbursement do not qualify as an "accepted guideline" when offered to limit treatment options otherwise covered within the Pain Relief Act." *(N.M. Stat. Ann § 24-2D-3)*

Note: Adopted from the Pain Relief Act (Project on Legal Constraints on Access to Effective Pain Relief, 1996).

OKLAHOMA – Controlled Substances Act

"D. The Oklahoma State Board of Medical Licensure and Supervision and the Oklahoma State Board of Osteopathic Examiners shall issue policies, guidelines or rules that ensure that physicians who are engaged in the appropriate treatment of pain are not subject to disciplinary action, and the Boards shall consider policies and guidelines developed by national organizations with expertise in pain medicine or in a medical discipline for this purpose." *(UCSA 63 Okl St 2-551)*

ARKANSAS – Medical Practice Act

"(a) (1) A physician shall not be subject to disciplinary action by the Arkansas State Medical Board solely for prescribing dangerous or controlled drugs for the relief of chronic intractable pain." *(A.C.A. § 17-95-701-707)*

NEVADA – Osteopathic Practice Act

"An osteopathic physician is not subject to disciplinary action solely for: 1. Prescribing or administering to a patient under his care…(c)A controlled substance which is listed in schedule II, III, IV or V by the State Board of Pharmacy pursuant to NRS 453.146, if the controlled substance is lawfully prescribed or administered for the treatment of intractable pain in accordance with accepted standards for the practice of osteopathic medicine." *(Nev. Rev. Stat. Ann § 633.521)*

NEBRASKA – Public Health and Welfare Act

"The Board of Examiners in Medicine and Surgery shall adopt policies and guidelines for the treatment of pain to ensure that physicians who are engaged in the appropriate treatment of pain are not subject to disciplinary action, and the board shall consider policies and guidelines developed by national organizations with expertise in pain management for this purpose." *(Public Health and Welfare 71-2420)*

UTAH – REGULATION – Professional Practice Regulations

"Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice." *(R156-1-502. Unprofessional Conduct)*

Note: Adapted from the Model Policy for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 2004)

ALABAMA – REGULATION – Medical Board Regulations

"Physicians should not fear disciplinary action from the Board, or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual courser of professional practice." *(540-X-4-.08)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

TENNESSEE – REGULATION – Osteopathic Board Regulations

"Physicians should not fear disciplinary action from the Board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice." *(1050-2-.13 Specifically Regulated Areas and Aspects of Medical Practice)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

FLORIDA – REGULATION – Pharmacy Board Regulations

"Pharmacists should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose." *(64B16-27.831, F.A.C. "Standards of Practice for the Dispensing of Controlled Substances for Treatment of Pain")*

NORTH CAROLINA – Medical Board Policy Statement

"No physician need fear reprisals from the Board for appropriately prescribing, as described above, even large amounts of controlled substances indefinitely for chronic non-malignant pain." *("Management of Chronic Non-Malignant Pain," issued by the North Carolina Board of Medical Examiners, September 13, 1996)*

ARIZONA – Osteopathic Board Guideline

"Physicians should not fear disciplinary action from the Board, or other state regulatory or enforcement agency for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice." *(Arizona Board of Osteopathic Examiners in Medicine and Surgery Guidelines. "The Prescribing of Controlled Substances for the Treatment of Pain Management." Effective: January 22, 2000)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

TEXAS – Pharmacy Board Policy Statement

"Pharmacists should not fear disciplinary action from the Board for dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice." *("Texas State Board of Pharmacy Position Statement on the Treatment of Pain," Adopted August 29, 2001)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

WEST VIRGINIA – Joint Board Policy Statement

"Health care professionals should not fear disciplinary action from the Board for prescribing, administering, or dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. All such prescribing must be established with clear documentation of unrelieved pain and in compliance with applicable state of federal law." *(West Virginia Examiners for Registered Professional Nurses, Medicine, Osteopathy, and Pharmacy Boards. "Joint Policy Statement on Pain Management at the End of Life." Adopted March 12, 2001)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

CRITERION #6. PRESCRIPTION AMOUNT ALONE IS RECOGNIZED AS INSUFFICIENT TO DETERMINE LEGITIMACY OF PRESCRIBING

In the past there has been a tendency to judge the legitimacy of a practice on the basis of the amount or duration of prescribing. However, a judgment based on such limited information is likely to yield "false positives" (i.e., identification of acceptable treatment as inappropriate). A decision about professional conduct should be made according to the adequacy of care in relation to professional standards. Some states have adopted standards of care that replace quantity and duration with an evaluation of the physician's treatment of the patient. This is in keeping with the Central Principle of Balance because it replaces an arbitrary standard with one that focuses on the physician's overall treatment of the patient.

VIRGINIA – STATUTE – Controlled Substances Act

"In the case of a patient with intractable pain, a physician may prescribe a dosage in excess of the recommended dosage of a pain relieving agent if he certifies the medical necessity for such excess dosage in the patient's medical record. Any person who prescribes, dispenses or administers an excess dosage in accordance with this section shall not be in violation of the provisions of this title because of such dosage, if such excess dosage, is prescribed, dispensed or administered in good faith for accepted medicinal or therapeutic purposes." *(CSA 54.1-3408.1)*

NEBRASKA – STATUTE – Public Health and Welfare Act

"(3) The Legislature finds that physicians should be able to prescribe, dispense, or administer a controlled substance in excess of the recommended dosage." *(Public Health and Welfare 71-2418 Legislative Findings)*

NEW MEXICO – STATUTE – Pain Relief Act

"D. In an action brought by a board against a health care provider based on treatment of a patient for pain, the board shall consider the totality of the circumstances and shall not use as the sole basis of the action....(6) the quantity of medication prescribed or dispensed." *(Pain Relief Act 24-2D-3 Disciplinary Action;*

TENNESSEE – REGULATION – Medical Board Regulations

"It is the position of the board that these drugs may be prescribed for the treatment of pain and other related symptoms after a reasonably based medical diagnosis has been made, in adequate doses, and for appropriate lengths of time, which in some cases may be as long as the pain or related symptoms persist." *(0880-2-.14, TAC)*

FLORIDA – REGULATION – Osteopathic Board Regulations

"The Board will judge the validity of prescribing based on the osteopathic physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing." *(64B15-14.005, F.A.C. Standards for the Use of Controlled Substances for Treatment of Pain)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

UTAH – REGULATION – Professional Practice Regulations

"The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration." *(R156-1-502. Unprofessional Conduct)*

Note: Adapted from the Model Policy for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 2004)

NEBRASKA – Medical Board Guidelines

"The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing." *("Guidelines for the Use of Controlled Substances for the Treatment of Pain" issued by the Kansas State Board of Healing Arts, October 17, 1998)*

Note: Adopted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

ARIZONA – Osteopathic Board Guideline

"The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on quantity and chronicity of prescribing." *(Arizona Board of Osteopathic Examiners in Medicine and Surgery Guidelines. "The Prescribing of Controlled Substances for the Treatment of Pain Management." Effective: January 22, 2000)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

TEXAS – Medical Board Policy Statement

Quantity and chronicity of prescribing will be judged on the basis of the diagnosis and treatment of the targeted symptoms and neither of these factors are prima facie evidence of inappropriate or excessive prescribing. *("Pain Control and the Texas State Board of Medical Examiners," Newsletter, Vol. 15, no. 1, Spring/Summer 1993, p. 1)*

CALIFORNIA – Pharmacy Board Policy Statement

"The Board understands that the ongoing use of opioids for cancer, post-surgical, and chronic pain is not what causes addiction or a patient's desire for higher doses of pain medication. Patients suffering from extreme pain or progression of disease may require increased doses of medication; the appropriate dose is that which is required to adequately treat the pain, even if the dose is higher than usually expected." *(California State Board of Pharmacy. "Dispensing Controlled Substances for Pain: A Statement of the California State Board of Pharmacy," Health Notes, p. 4-5, 1996)*

CRITERION #7. PHYSICAL DEPENDENCE OR ANALGESIC TOLERANCE ARE *NOT* CONFUSED WITH "ADDICTION"

It may be preferable not to include medical terminology (including addiction-related terms) in statutes or regulations because such terminology evolves in a dynamic field such as pain management. Incorrect, archaic, or ambiguous terminology, such as "habitue" or "drug dependent person," can be confusing and can inappropriately narrow allowable medical treatment by stigmatizing opioid analgesics and the patients who use them in treatment. Thus, policymakers should consider carefully the necessity and appropriateness of using and defining medical terms in statutes or regulations.

Considerable misunderstanding exists about what "addiction" is and is not. Medical and scientific knowledge about pain physiology and opioid pharmacology have clarified the difference between "addiction," and physical dependence and analgesic tolerance. Policy language, however, often does not reflect this distinction. *When policies contain inaccurate definitions of addiction-related terms, repeal is the first choice.* If this is not possible, definitions can be modified to clarify the critical distinction and prevent further confusion.

UNIFORM CONTROLLED SUBSTANCES ACT

"If a State chooses to use [a definition for such terms as "addict," "drug dependent person," or "habitual user"], the State should assure that the definition can not be construed to include a patient using a controlled substance pursuant to the lawful order of a practitioner." *(National Conference of Commissioners on Uniform State Laws, 1994)*

LOUISIANA – STATUTE – Controlled Substances Act

"(38) 'Substance abuse' or 'addiction' means a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological, or physical consequences, the continued use of which results in a decreased quality of life. The development of controlled dangerous substance tolerance or physical dependence does not equate with substance abuse or addiction." *(La. R.S. 40:961 Definitions)*

FLORIDA – REGULATION – Medical Board Regulations

"Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction." *(64B8-9.013, FAC)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

TENNESSEE – REGULATION – Osteopathic Board Regulations

"Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction." *(1050-2-.13 Specifically Regulated Areas and Aspects of Medical Practice)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

UTAH – REGULATION – Professional Practice Regulations

"Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction." *(R156-1-502. Unprofessional Conduct)*

Note: Adapted from the Model Policy for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 2004)

ARIZONA – Osteopathic Board Guideline

"Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction." *(Arizona Board of Osteopathic Examiners in Medicine and Surgery Guidelines. "The Prescribing of Controlled Substances for the Treatment of Pain Management." Effective: January 22, 2000)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

TEXAS – Medical Board Policy Statement

"Tolerance and physical dependence are normal consequences of sustained use of these drugs and are not synonymous with psychological dependency (addiction) on them. Psychological dependency is characterized by the compulsion to take the drug despite its harmful and destructive effect on the individual." *(Texas State Board of Medical Examiners Newsletter, Volume 15, no. 1, Spring/Summer 1993)*

CALIFORNIA – Pharmacy Board Policy Statement

"In addition, with long-term treatment of pain with opioids, patients may develop a tolerance to the drug or a dependence on the drug. These occurrences are considered 'normal' and 'to be expected' - they should not be confused by the licensed healthcare professional with drug addiction or be mislabeled as "drug seeking." *(California State Board of Pharmacy "Health Notes: Pain Management," 1996, pp. 4-5)*

WEST VIRGINIA – Joint Policy Statement

"Health care professionals should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction." *(West Virginia Boards of Examiners for Registered Nurses, Medicine, Osteopathy, and Pharmacy. "Joint Policy Statement on Pain Management at the End of Life." Effective: March 12, 2001)*

Note: Adapted from the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Federation of State Medical Boards of the United States, Inc., May 1998)

PART B. Provisions That May Impede Pain Management

It is advisable to repeal provisions that, if implemented, could impede effective pain management; this section indicates the extent that some states have removed potential barriers from controlled substances or professional practice policies.

CRITERION #9. OPIOIDS ARE CONSIDERED A TREATMENT OF LAST RESORT

Most policies are appropriately silent on specific medical and pharmacologic matters. However, a number of states have language that directly states that the medical use of opioids is or should be, as a matter of policy, a treatment of last resort. These should be repealed as they are inconsistent with medical knowledge and clinical practice. In general, it is preferable for government to avoid characterizing the role of medicine and drugs in the treatment of pain; law should permit rather than direct the course of medicine so that it can follow science and clinical experience. Restrictive language in the context of policies that determine the legality of the use of controlled substances in professional practice for all patients could have unintended consequences.

To date, Arizona, Georgia, Ohio, Virginia, and West Virginia have repealed provisions that define the use of controlled substances as a treatment of last resort.

CRITERION #10. MEDICAL USE OF OPIOIDS IS IMPLIED TO BE OUTSIDE LEGITIMATE PROFESSIONAL PRACTICE

Some states have language that implies that the medical use of opioids for chronic pain is questionable, and therefore at the periphery (or even outside) of ordinary professional practice, and consequently illegal. For example, some state policies have definitions of "intractable pain" that carry this implication. Such provisions should be repealed. The appropriate recognition of opioids, pain, and medical practice can be achieved by adopting provisions from Part A of this section relating to Criterion #1, Criterion #2, and Criterion #3.

Examples: In 2002, the states of Iowa and Michigan eliminated all use of the word "intractable" when they revised pain-related policy. North Dakota and Rhode Island made similar changes to their state statutes in 2005. In 2006, Arizona, California, and Texas repealed the definition of "intractable pain" from a medical board policy statement, statute, and medical board regulation, respectively. In 2007, Oregon repealed the definition of "intractable pain" from statute.

CRITERION #11. PHYSICAL DEPENDENCE OR ANALGESIC TOLERANCE ARE CONFUSED WITH "ADDICTION"

If policies contain addiction-related terms that confuse addiction with the physical dependence or tolerance that may occur during opioid treatment of persistent pain, they should be repealed or defined more accurately. This action, if communicated to the public, health professionals, and regulators, may help to rectify the long-standing suspicion that chronic pain patients using opioids are addicted or drug dependent. Such provisions can be found in Part A of this section relating to Criterion #7.

Rhode Island was the first state to repeal an inaccurate addiction-related definition from state law; a number of states have recently adopted board policies that have correct definitions, including Georgia, Kansas, Kentucky, Louisiana, Missouri, Nevada, Texas, and West Virginia.

CRITERION #12. MEDICAL DECISIONS ARE RESTRICTED

Decisions about patient care should be made by the treating practitioner based on examination of the individual patient and the application of medical expertise, rather than being dictated by the government. Practitioners need to have flexibility to respond to the treatment needs of individual patients, which can vary greatly even among patients with the same disease or condition. If the evaluation of state policies identifies any of the four types of provisions that have the potential to interfere with medical decisions outlined in Criterion #12, these should be amended or repealed.

Examples:
Category A – Patient Characteristics: In 1997, Texas amended its policy to allow prescribing to patients who are currently abusing or who have a history of substance abuse. North Dakota repealed the same provision in 2005, as did California in 2006.

Category B – Mandatory Consultation: To date, Arizona, California, Colorado, Idaho, Iowa, Kentucky, Massachusetts, Michigan, New Mexico, North Dakota, Oregon, Rhode Island, Vermont, Virginia, and West Virginia have repealed policy language that requires physicians to obtain consultations when using opioids to treat pain.

Category C – Quantity Prescribed or Dispensed: In 2001, Wisconsin repealed an overly restrictive dosage unit limitation (a 34-day supply).

Category D – Undue Prescription Limitations: In 2003, Kentucky eliminated a medical regulatory recommendation for drug holidays when using opioids to treat pain, as did Georgia in 2008.

CRITERION #13. LENGTH OF PRESCRIPTION VALIDITY IS RESTRICTED

In a balanced drug control policy, efforts to reduce drug diversion should not interfere with providing medications to the patient. Unrealistically short prescription validity periods can interfere with a physician's ability to provide medications, as well as a patient's ability to obtain them without having to make extraordinary and sometimes expensive arrangements. Neither the federal Controlled Substances Act nor federal regulations limit the period of time that a prescription may be dispensed after it has been issued. Similarly, most states do not impose a validity period. Validity periods should be repealed or amended to be realistic.

Examples: The following states have repealed or lengthened overly restrictive prescription validity periods: Idaho (7 days), Michigan (5 days), Rhode Island (7 days), Texas (7 days), and Wisconsin (7 days).

CRITERION #14. PRACTITIONERS ARE SUBJECT TO ADDITIONAL PRESCRIPTION REQUIREMENTS

Some states have enacted laws requiring physicians to use a special government-supplied prescription form to prescribe certain controlled substances (typically only those in Schedule II). Increasingly, states are adopting policy to electronically monitor prescribing and dispensing without using government-issued prescription forms, and for multiple schedules of medications.

Examples: In 1994, Indiana became the first state to switch from a special prescription form (triplicate) to an EDT system without requiring a government-issued prescription form. Since then, a number of states have likewise transitioned to a system without a government-issued prescription form for Schedule II controlled substances: California (2005), Hawaii (2002), Idaho (2001), Illinois (1999), Michigan (2002), New York (2005), and Rhode Island (1997).

APPENDIX A:
FEDERATION OF STATE MEDICAL BOARD'S
MODEL POLICY FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

(Adopted May, 2004)

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering**,** prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

1. Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

a. urine/serum medication levels screening when requested;
b. number and frequency of all prescription refills; and
c. reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

5. Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records—The physician should keep accurate and complete records to include

a. the medical history and physical examination,
b. diagnostic, therapeutic and laboratory results,
c. evaluations and consultations,
d. treatment objectives,
e. discussion of risks and benefits,
f. informed consent,
g. treatments,
h. medications (including date, type, dosage and quantity prescribed),
i. instructions and agreements and
j. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to *the Physicians Manual of the U.S. Drug Enforcement Administration* and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury**,** or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

APPENDIX B:
RECOMMENDED READINGS

The following material provides background information on pain, controlled substances, and professional practice:

- American Academy of Pain Medicine, American Pain Society, American Society of Addiction Medicine. *Definitions Related to the Use of Opioids for the Treatment of Pain*. Glenview, IL: AAPM, APS, ASAM; 2001. http://www.ampainsoc.org/advocacy/opioids2.htm

- Cleary JF. The pharmacologic management of cancer pain. *Journal of Palliative Medicine.* 2007;10:1369-1394.

- Dahl JL. Working with regulators to improve the standard of care in pain management: The U.S. experience. *Journal of Pain & Symptom Management*. 2002; 24(2):136-146.

- Drug Enforcement Administration. Issuance of multiple prescriptions for Schedule II controlled substances. Docket No. DEA-287F. *Federal Register*; 72[222]:64921-64930. November 19, 2007. http://www.deadiversion.usdoj.gov/fed_regs/rules/2007/fr1119.htm

- Drug Enforcement Administration. *Practitioner's manual: A guideline to the practitioner's responsibilities under the Controlled Substances Act of 1970*. Washington, DC: United States Department of Justice; 2006. http://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html

- Drug Enforcement Administration, Last Acts, Pain & Policy Studies Group, et al. *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*. Washington, DC: Last Acts; 2001. http://www.painpolicy.wisc.edu/dea01.htm

- Fishman SM. Responsible opioid prescribing: A physician's guide. Washington, DC: Waterford Life Sciences, 2007.

- Gilson AM, Joranson DE. Controlled substances and pain management: Changes in knowledge and attitudes of state medical regulators. *Journal of Pain & Symptom Management.* 2001; 21(3):227-237. http://www.painpolicy.wisc.edu/publicat/01jpsm/jpsm01.pdf

- Gilson AM, Joranson DE, Maurer MA. Improving state medical board pain policies: Influence of a model. *Journal of Law, Medicine & Ethics.* 2003; 31(1):119-129. http://www.painpolicy.wisc.edu/publicat/03jlme/jlme_model.pdf

- Gilson AM, Joranson DE, Maurer MA, Ryan KM, Garthwaite JP. Progress to achieve balanced state policy relevant to pain management and palliative care: 2000-2003. *Journal of Pain & Palliative Care Pharmacotherapy*. 2005; 19(1):7-20. http://www.painpolicy.wisc.edu/publicat/05jppcp/05jppcp.pdf

- Gilson AM, Maurer MA, Joranson DE. State policy affecting pain management: Recent improvements and the positive impact of regulatory health policies. *Health Policy*. 2005; 74(2):192-204. http://www.painpolicy.wisc.edu/publicat/05hlthpol/05hlthpol.pdf

- Gilson AM, Ryan KM, Joranson DE, Dahl JL. A reassessment of trends in the medical use and abuse of opioid analgesics and implications for diversion control: 1997-2002. *Journal of Pain & Symptom Management*. 2004; 28(2):176-188. http://www.painpolicy.wisc.edu/publicat/04jpsm/04jpsm.pdf

- Hoffmann DE, Tarzian AJ. Achieving the right balance in oversight of physician opioid prescribing for pain: The role of state medical boards. *Journal of Law, Medicine & Ethics*. 2003; 31(1):21-40.

- Joranson DE. Guiding principles of international and federal laws pertaining to medical use and diversion of controlled substances. In: Cooper JR et al. *Evaluation of the Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care: Possible Implications for Future Research*. National Institute on Drug Abuse Technical Research Monograph 131. Rockville, MD: NIDA, 1993.

- Joranson DE, Carrow GM, Ryan KM, et al. Pain management and prescription monitoring. *Journal of Pain & Symptom Management.* 2002; 23(3):231-238. http://www.painpolicy.wisc.edu/publicat/02jpsm2/pmp.pdf

- Joranson DE, Gilson AM. Wanted: A public health approach to prescription opioid abuse and diversion [Editorial]. *Pharmacoepidemiology and Drug Safety*. 2006;15:632-634. http://www3.interscience.wiley.com/cgi-bin/jissue/85510548?CRETRY=1&SRETRY=0

- Joranson DE, Gilson AM. Drug crime is a source of abused pain medications in the United States [Research Letter]. *Journal of Pain & Symptom Management*. 2005; 30(4):299-301. http://www.sciencedirect.com/science?_ob=MImg&_imagekey=B6T8R-4HDPX61-1-1&_cdi=5093&_user=443835&_orig=browse&_coverDate=10%2F31%2F2005&_sk=999699995&view=c&wchp=dGLbVzb-zSkWz&md5=7d061305721e33d820fadb2e58fa4ce8&ie=/sdarticle.pdf

- Joranson DE, Gilson AM. Pharmacists' knowledge of and attitudes toward opioid pain medications in relation to federal and state policies. *Journal of the American Pharmaceutical Association*. 2001; 41:213-220. http://www.painpolicy.wisc.edu/publicat/01japhak/01japhak.pdf

- Joranson DE, Gilson AM, Nischik JA. North Carolina, pain management and end-of-life care: Communicating the policy. *Federation Bulletin, Journal of Medical Licensure & Discipline.* 2002; 88(3):116-119. http://www.painpolicy.wisc.edu/publicat/02fsmb/jmld02.pdf

- Joranson DE, Gilson AM, Dahl JL, Haddox JD. Pain management, controlled substances, and state medical board policy: A decade of change. *Journal of Pain & Symptom Management.* 2002; 23(2):138-147. http://www.painpolicy.wisc.edu/publicat/02jpsm1/jpsm02.pdf

- Jung B, Reidenberg MM. The risk of action by the Drug Enforcement Administration against physicians prescribing opioids for pain. *Pain Medicine*. 2006;7(4):353-357.

- Katz NP, Adams EH, Benneyan JC, Birnbaum HG, Budman SH, Buzzeo RW et al. Foundations of opioid risk management. *Clinical Journal of Pain.* 2007; 23(2):103-118.

- Lorenz KA, Shugarman LR, Lynn J. Health care policy issues in end-of-life care. *Journal of Palliative Medicine.* 2006; 9(3):731-748.

- Pain & Policy Studies Group. Matrix of state pain policies: full-text database. 2008. http://www.painpolicy.wisc.edu/matrix.htm

- Pain & Policy Studies Group. Website Matrix of State Continuing Medical Education Policies for Pain and Palliative Care. 2008. http://www.painpolicy.wisc.edu/domestic/cme.htm

- Richard J, Reidenberg M. The risk of disciplinary action by state medical boards against physicians prescribing opioids. *Journal of Pain & Symptom Management*. 2005; 29(2):206-212.

- Wisconsin Controlled Substances Board. *Memorandum of cooperation for controlling diversion of controlled substances in Wisconsin.* Cooperative agreement among the Wisconsin Controlled Substances Board, Pharmacy Examining Board, Medical Examining Board, Dentistry Examining Board, Veterinary Examining Board, and U.S. Drug Enforcement Administration. Effective 5/28/80 to 6/30/83.

APPENDIX C:
WHAT CAN STATE LEGISLATURES AND AGENCIES DO TO IMPROVE PAIN MANAGEMENT?

The initial, crucial, step legislatures and state agencies can take to improve pain management is to study the problem. Although the problems and solutions differ from state to state, one state often can benefit from the efforts and experiences of others, so reviewing what other states have done is recommended

The most common and probably the most valuable method is to create a multidisciplinary task force, commission, or advisory committee to study carefully the legal, fiscal, and other barriers to pain management for all types of pain patients in the state (chronic cancer and non-cancer, post-surgical, sickle-cell, HIV/AIDS, etc). For this process it is important to review relevant state policies outlined below and throughout this report, and then make and implement recommendations in legislation (policy, budget), regulations, guidelines, public information, education, training, program development, etc. States with sunrise/sunset review criteria should consider subjecting those statutes and regulations that affect pain management to those criteria (in addition to the criteria set out in this *Evaluation Guide*).

1. Controlled substances policy

Does the state Controlled Substances Act recognize the essential medical uses of controlled substances, as in federal law and as recommended by the National Conference of Commissioners on Uniform State Laws?

Do state statutes or regulations unduly restrict prescribing of controlled substances, such as:

- requiring government prescription forms for Schedule II controlled substances only;
- including legal terminology that would label pain patients as "addicts";
- limiting number of dosage units or durations of controlled substances (e.g., opioids) that can be prescribed at one time; or
- limiting the period of validity of a prescription for a controlled substance?

2. Healthcare policy

Do the relevant practice acts or board regulations contain any provisions that are unduly restrictive or confusing when applied to the prescribing of controlled substances for the treatment of pain (e.g., no prescribing to patients with an addictive disease, even if they have pain, or requiring second opinion or consultation before prescribing for pain)? Are the boards' statutes, regulations, and guidelines adequately disseminated or available to licensees and others?

Have the boards of medicine, osteopathy, pharmacy, and nursing adopted guidelines or policies clarifying that the board recognizes that the use of controlled substances for the treatment of pain is accepted professional practice and setting forth the principles that a practitioner can follow to confidently avoid the risk of disciplinary sanctions by a regulatory agency in the state?

Do the state's professional schools for medicine, pharmacy, and nursing provide adequate instruction about pain and palliative care?

3. Facility regulation (hospital, hospice, nursing home, home care, etc.)

What is the attitude of the state regulators of health care facilities? Is pain a priority or is the priority to reduce the use of controlled drugs? Do licensing, certification, or inspection criteria include assessment and treatment of pain and training of patient care staff? Is technical assistance on pain and symptom management available?

Are there inappropriate restrictions, requirements, formularies, or financial constraints on the delivery of pain management?

4. State health policy

Are there inappropriate financial constraints on the delivery of pain management? Do managed care organizations have policies addressing pain assessment, treatment, reimbursement, and appropriate access to specialists?

Does state Medicaid policy adequately reimburse the controlled drugs used in pain and symptom management? Does it unduly restrict which drugs are covered and in what amounts?

Does Workers Compensation adequately address the needs of people with chronic severe pain?

Does the state cancer control plan emphasize pain management and palliative care for cancer patients in the state? Does the plan include actions that should be taken to improve state policy and access to quality pain and palliative care.

Is there a State Pain Initiative or other pain and palliative care organization that advocates for improved pain management and policy? Is there adequate communication between government agencies and state pain initiatives or leading pain practitioners? Do state regulators participate in the initiative's activities?

Does the public have access to information about pain and symptom management including cancer and chronic non-cancer pain, and where to go for help? Are any organizations undertaking proactive efforts to provide information?

Does the toll-free number for cancer information also include information about pain management?

5. Law enforcement and regulatory policy

Do the state agencies that are involved in drug law enforcement and monitoring of controlled substances prescribing, dispensing, and patient use have adequate safeguards against the inappropriate scrutiny of practitioners who legitimately prescribe and dispense controlled substances and the maintenance of confidentiality of patient information (i.e., what standards do they use for initiating or continuing investigations, or what input do they get in establishing standards and from whom)? Have state legal officials (such as the Attorney General) reviewed state policies relevant to pain management and end-of-life matters, such as advance directives and durable power of attorney, as recommended by the National Association of Attorneys General?

APPENDIX D:
REGULATORY SYSTEMS AND PAIN MANAGEMENT

The purpose of this section is to describe briefly the regulatory systems and recent trends that affect pain management. References are provided for more extensive information.

There are several regulatory systems that influence access to and delivery of pain management. These include the regulation of patient care facilities, reimbursement, drug regulation, and the licensing of health professionals. This section discusses the latter two.

Drug regulation

There are three tiers of drug regulation: International, federal, and state. The latter two will be discussed here; publications about international regulation are available on the PPSG website at www.painpolicy.wisc.edu.

Federal and state laws provide for three general levels of drug control, including "over-the-counter" drugs, "prescription" drugs, and "controlled substances." Under federal and state laws, over-the-counter drugs, such as aspirin, are the least controlled and are available directly to the consumer at a wide variety of retail establishments without a physician's order. Prescription drugs, such as antibiotics, which have greater potency and risks, must be approved as safe and effective for human use by the FDA according to authority under the Federal Food, Drug and Cosmetic Act. Their availability for medical use is pursuant to a prescription from a physician, dentist, podiatrist, or other professional licensed to prescribe. Prescription drugs also are regulated at the state level by food and drug laws, and by pharmacy laws that typically are administered by state pharmacy boards. Manufacturers and wholesalers are subject to provisions regarding the production, marketing, advertising, and distribution of prescription drugs. Federal and state laws provide penalties for obtaining prescription drugs without a prescription. As a class, prescription drugs may be prescribed for other than their specifically labeled indications if there is a medical rationale.

Controlled substances laws provide an additional layer of control over the distribution of prescription drugs that have a potential for producing psychological or physical dependence, as a means of preventing abuse, trafficking, and diversion. The federal Controlled Substances Act (CSA) contains numerous provisions regarding the possession, manufacture, and trafficking in illicit controlled substances, for which criminal penalties are established; at the same time, the CSA recognizes that controlled substances are necessary for public health and that their availability for medical and scientific purposes must be assured. Therefore, despite increased control measures, the requirements of the CSA are not intended to interfere with the medical uses of prescription drugs. The CSA specifies five classification schedules that carry different penalties for unlawful uses; requirements for prescriptions also vary depending on the schedule. Schedule I contains all drugs that have no approved medical use, such as the opioid heroin. Schedules II-IV contain drugs that have been approved by the FDA for medical use, including the opioids. Opioids with the highest potential for abuse are in Schedule II and include morphine, hydromorphone, methadone, oxycodone, and fentanyl. Opioids such as hydrocodone combinations and codeine combinations are in Schedule III, while Schedule IV also contains codeine in smaller dosages. Schedule V contains some opioids in smaller amounts, which may be over-the-counter cough preparations. All schedules also include non-opioids.

Under the CSA, it is not lawful for practitioners to use Schedule II drugs (i.e., methadone) for the purpose of maintenance or detoxification of narcotic addiction; this activity requires separate registration by the federal government and in some states. The use of drugs approved for this purpose, such as methadone and buprenorphine (which is in Schedule III), must be in

compliance with federal and state regulations. Methadone, however, may be prescribed as an analgesic according to the same rules for prescribing any other Schedule II opioid analgesic.

All persons or business entities must be registered with the Drug Enforcement Administration (and with state agencies in some states) to manufacture, distribute, handle, dispense or prescribe controlled substances. Registrants' purchases of Schedule II controlled substances and Schedule III narcotics are made using a special order form to monitor all transfers of these controlled substances within a "closed system." Prescriptions for Schedule II drugs must be written and may not be refilled, while five refills are permitted for drugs in Schedules III and IV. Federal law allows oral or faxed (but not electronic transmission) of prescriptions of controlled substances in Schedule II in medical emergencies under specific circumstances. Federal law also allows for the partial dispensing and faxing (but not oral or electronic data transmission) of prescriptions under certain circumstances. Federal laws do not limit the amount of the prescription or the duration of prescribing. There are penalties, both criminal and civil, for violation of federal requirements. The federal requirements are available at http://www.access.gpo.gov/nara/cfr/waisidx_03/21cfrv9_03.html.

The states have adopted versions of the CSA that use the same classification system, generally using a model Uniform Controlled Substances Act (UCSA) prepared by the National Conference of Commissioners on Uniform State Laws in 1970. All of the state Acts permit prescribing of controlled substances in Schedules II - V, although most do not specifically reflect the recognition by federal law of the medical uses of controlled substances. A 1994 revision of the model UCSA was prepared to correct these deficiencies, but only a few states have adopted the changes. The criminal provisions of the state Acts are enforced by state and local police agencies, while the drug regulatory aspects of state controlled substances laws are administered by a variety of state agencies, including departments of regulation and licensing (e.g., medical or pharmacy boards). These agencies often have regulations that govern the prescribing and dispensing of controlled substances more so than under federal law. Penalties for violation of prescribing requirements vary greatly. Some states also limit the amount that can be prescribed at one time, and limit the validity of a controlled substance prescription to a few days or a week. Some have overly broad definitions of "addict" that could include physically dependent pain patients; some states prohibit prescribing to persons with an addictive disease, or require they be reported to a state agency.

A number of years ago, some states began enacting "Prescription Monitoring Programs" (PMPs) that require the physician to use government-issued prescription forms when prescribing controlled substances in certain schedules (see Table 3). The purpose of PMPs is to provide law enforcement, prescribers, and dispensers with information on "doctor shoppers," "scammers," and dishonest physicians. Although representatives of PMPs indicate that such programs are not intended to interfere with medical practice, and that precautions are taken to avoid interference, some in the medical field expressed concern that PMPs (which required a government-issued prescription form for Schedule II controlled substances only) have a "chilling effect" on physician prescribing due to physician fear of being investigated for excessive prescribing. Indeed, several studies have shown that, after implementation of such programs, the prescribing of Schedule II medications being monitored declined substantially, and may have caused an increase in the prescribing of drugs in lower (less restricted) schedules that may have been less appropriate clinically for the patient's condition. This decline in prescribing has been interpreted by law enforcement authorities to indicate a reduction in inappropriate prescribing.

Since the mid 1990s, states began to adopt PMPs that use electronic data transmission (EDT) systems. The EDT system requires the pharmacist to send prescription information electronically

to the state agency that administers the program, which can obviate the need for a government-issued prescription form. Most of these EDT programs monitor medications at least in Schedules II-IV (not just Schedule II) and do not require a government-issued prescription form. (However, one state continues to use a government-issued form for Schedule II controlled substances in conjunction with an EDT program.) See Table 3 for a description of current prescription monitoring programs.

Regulation of healthcare professionals

The regulation of professional practice in medicine, osteopathy, pharmacy, nursing, and other professions occurs at the state, not federal, level (although federal agencies substantially affect professional practice by denying or revoking controlled substances registration). State legislatures have adopted statutes to protect the public; these provide authority for a state agency to license and discipline members of the profession. Typically, the law creates a board, such as a medical board, that is responsible for licensing the members of the profession, as well as disciplining licensees for violating standards of professional conduct (these are usually expressed in the board's statute or in regulations). Boards have the power to adopt regulations to implement their statutory authority. The enactment of statutes and adoption of regulations are both subject to public scrutiny and, generally, public comment. A fixed number of board members with staggered terms typically is appointed by the Governor, sometimes in consultation with the profession's state society and sometimes with several appointments by the Legislature. Typically, there will be at least some members who are not licensees of the board, called "public members."

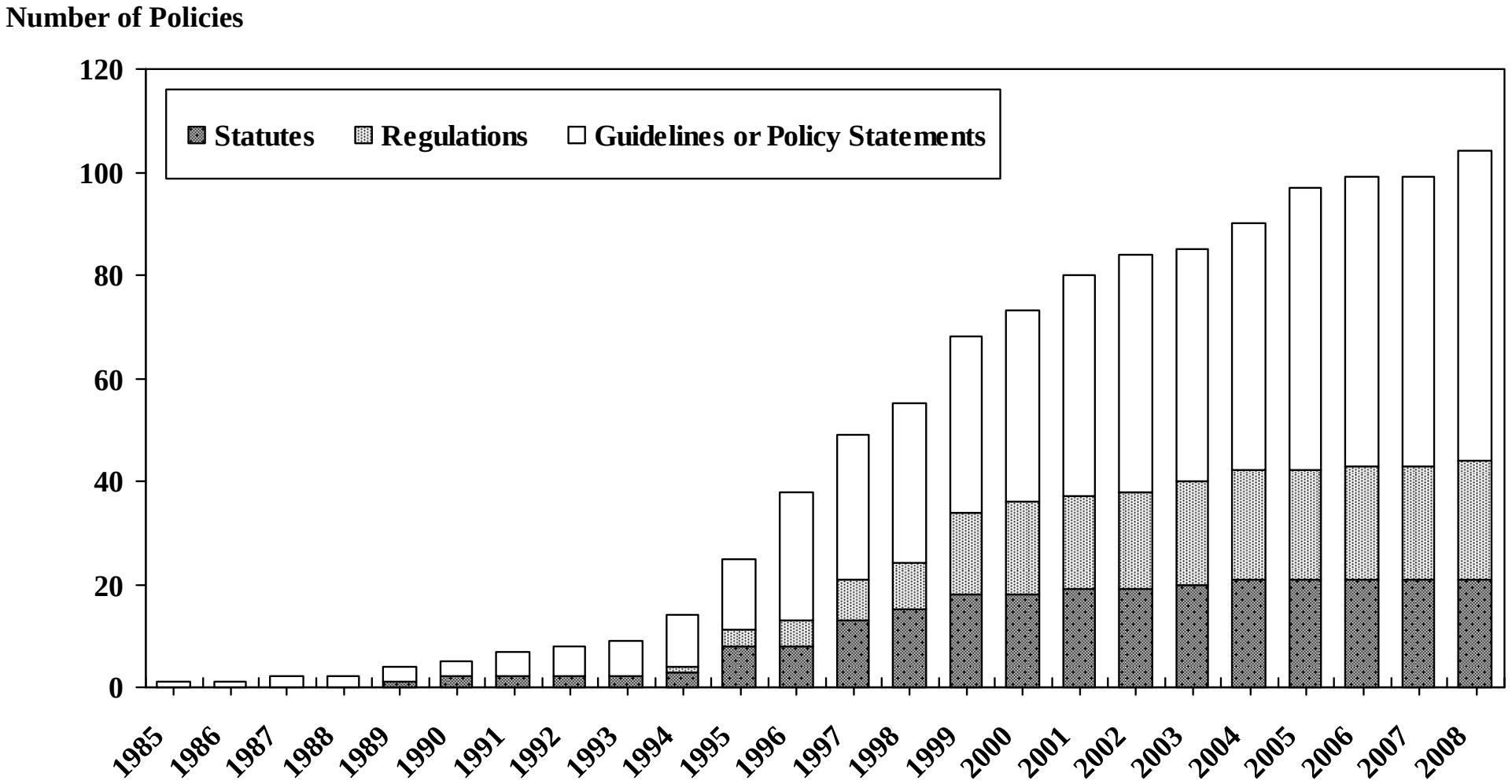
Board investigation of a licensee is usually initiated by a complaint or by referral from another agency. Boards differ greatly as to the procedures used for inquiry and investigation into complaints – some boards are required by law to investigate each complaint received, while others can exercise discretion. Investigations may or may not be prompt, and may be dropped due to insufficient evidence or may proceed to disciplinary action, which can range from a warning, to education, to a limitation or removal of prescribing privilege or of the professional license. Board disciplinary actions are conducted pursuant to the state's Administrative Procedure Act; the licensee may appeal the decision to state courts. Boards also manage non-disciplinary programs to assist in the identification, treatment, and recovery of impaired professionals.

Each category of professional licensing board has a national organization that serves all the state boards – for medical boards it is the Federation of State Medical Boards; for pharmacy boards it is the National Association of Boards of Pharmacy; for nursing boards it is the National Council of State Boards of Nursing. The national organizations can be involved in a number of activities, such as: (1) the sponsorship of annual meetings, (2) the appointment of study task forces to address specific issues relevant to the regulation of that profession, and (3) a range of other technical assistance and information activities, including newsletters, statistics about licenses and discipline, and preparation of model statutes, regulations, and professional practice guidelines.

Figure 1.

Recent Trends in State Pain-Specific Policy

1985 - 2008



By: University of Wisconsin Pain & Policy Studies Group, 2008

Table 1:
International Authoritative Sources

International Narcotics Control Board. Demand for and supply of opiates for medical and scientific needs. In: *Report of the International Narcotics Control Board for 1989*. New York, NY: United Nations, 1989.

International Narcotics Control Board. Availability of opiates for medical needs. In: *Report of the International Narcotics Control Board for 1995*. New York, NY: United Nations, 1996.

International Narcotics Control Board. Report of the International Narcotics Control Board for 2005. New York, NY: United Nations, 2006.

International Narcotics Control Board. Report of the International Narcotics Control Board for 2006. New York, NY: United Nations, 2007.

United Nations. *Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961*. New York, NY: UN, 1977.

United Nations Economic and Social Council. *Treatment of pain using opioid analgesics; Resolution 2005-25*. Report on the forty-eighth session of the Commission on Narcotic Drugs E/2005/28; 19 March 2004 and 7-11 March 2005; issued 22 July 2005.

United Nations Economic and Social Council. *Demand for and supply of opiates used to meet medical and scientific needs; Resolution 2005-26*. Report on the forty-eighth session of the Commission on Narcotic Drugs E/2005/28; 19 March 2004 and 7-11 March 2005; issued 22 July 2005.

World Health Assembly. *Cancer prevention and control. WHA 58.22*. Geneva, Switzerland: World Health Organization; 2005.

World Health Organization. *Cancer pain relief*. Geneva, Switzerland: WHO, 1986.

World Health Organization. *Cancer pain relief and palliative care: Report of a WHO expert committee* (Technical Report Series 804). Geneva, Switzerland: WHO, 1990.

World Health Organization. *WHO expert committee on drug dependence* (Technical Report Series 836). Geneva, Switzerland: WHO, 1993.

World Health Organization. *Cancer pain relief with a guide to opioid availability* (Second edition). Geneva, Switzerland: WHO, 1996.

World Health Organization. *The use of essential drugs: Report of a WHO expert committee* (Technical Report Series 882). Geneva, Switzerland: WHO, 1998.

World Health Organization. *Achieving balance in national opioids control policy: Guidelines for assessment*. Geneva, Switzerland: World Health Organization; 2000.

World Health Organization. *National Cancer Control Programmes: Policies and managerial guidelines*. (Second ed.) Geneva, Switzerland: World Health Organization; 2002.

World Health Organization Executive Board. *Cancer control: Report by the Secretariat*. 114th Session. EB114/3. Geneva, Switzerland: World Health Organization, 2004.

World Health Organization. WHO expert committee on drug dependence: thirty-fourth report. Geneva, Switzerland: World Health Organization, 2006.

Table 2:
National Authoritative Sources

Cancer Pain Management Policy Review Group. *American Cancer Society position statement on regulatory barriers to quality cancer pain management*. National Government Relations Department, American Cancer Society; 2001.

Code of Federal Regulations. Title 21. Part 1300-1316.

Controlled Substances Act of 1970. Pub L No 91-513, 84 Stat 1242.

Drug Enforcement Administration. *Pharmacist's manual: An informational outline of the Controlled Substances Act of 1970*. U.S. Department of Justice: DEA, 2004.

Drug Enforcement Administration - Office of Diversion Control. *Prescription accountability resource guide*. Washington, DC: Drug Enforcement Administration; 1998.

Drug Enforcement Administration, Last Acts, Pain & Policy Studies Group, et al. *Promoting pain relief and preventing abuse of pain medications: A critical balancing act*. Washington, DC: Last Acts; October 2001.

Federal Food Drug and Cosmetic Act. *Title 21 USCS Chapter 9, 1938*.

Federation of State Medical Boards of the United States. *A guide to the essentials of a Modern Medical Practice Act* (Ninth edition). Dallas, TX: FSMB, 2000.

Federation of State Medical Boards of the United States. *Model policy for the use of controlled substances for the treatment of pain*. Euless, TX: FSMB, May 2004.

Institute of Medicine Committee on Opportunities in Drug Abuse Research. *Pathways of addiction: Opportunities in drug abuse research*. Washington, DC: National Academy Press; 1996.

Institute of Medicine. *Approaching death: Improving care at the end of life*. Washington, DC: National Academy Press, 1997.

Institute of Medicine National Cancer Policy Board. *Improving palliative care for cancer*. Foley KM, Gelband H, editors. Washington, DC: National Academy Press; 2001.

Institute of Medicine Committee on Cancer Control in Low- and Middle-Income Countries. Cancer control opportunities in low- and middle-income countries. Washington, DC: The National Academies Press, 2007.

National Association of Attorneys General. *Resolution calling for a balanced approach to promoting pain relief and preventing abuse of pain medications*. Adopted at the National Association of Attorneys General Spring Meeting; Washington, DC; March 17-20, 2003.

National Association of Attorneys General. *Improving end-of-life care: The role of Attorneys General*. Washington, DC: National Association of Attorneys General, 2003.

National Conference of Commissioners on Uniform State Laws. *Uniform Controlled Substances Act*. St. Louis, MO: NCCUSL, August 1-August 7, 1970.

National Conference of Commissioners on Uniform State Laws. *Uniform Controlled Substances Act*. Milwaukee, WI: NCCUSL, July 13-July 20, 1990.

National Conference of Commissioners on Uniform State Laws. *Uniform Controlled Substances Act*. Chicago, IL: NCCUSL, July 29-August 5, 1994.

National Institutes of Health Consensus Development Program. *Symptom management in cancer: Pain, depression and fatigue*. Statement prepared following a National Institutes of Health State-of-the-Science Conference on Symptom Management in Cancer; Bethesda, MD; July 15-17, 2002.

Table 3:

States with Prescription Monitoring Programs

State	Year Program Was Enacted	Current Program Type	Schedules/ drugs covered	Initial Program(s) Type	Year Previous Program Enactment
Alabama	2004	Electronic	C-II, III, IV, V		
Arizona	2007	Electronic	C-II, III, IV		
California	2005	Electronic/single-copy serialized security form	C-II, III, IV, V	Triplicate, serialized/Electronic Triplicate alone	1996 1939
Colorado	2005	Electronic	C-II, III, IV, V		
Connecticut	2006	Electronic	C-II, III, IV, V		
Hawaii	2002	Electronic	C-II, III, IV	Duplicate/Electronic Duplicate	1996 1943
Idaho	2001	Electronic	C-II, III, IV, V	Duplicate/Electronic Triplicate	1997 1967
Illinois	1999	Electronic	C-II	Triplicate	1961
Indiana	2004	Electronic	C-II, III, IV, V	Electronic, C-II only Triplicate	1994 1987
Iowa	2006	Electronic	C-II, C-III & IV as determined by advisory council		
Kentucky	1998	Electronic	C-II, III, IV, V		
Louisiana	2006	Electronic	C-II, III, IV, V as determined by advisory council		
Maine	2003	Electronic	C-II, III, IV		
Massachusetts	1992	Electronic	C-II		
Michigan	2002	Electronic	C-II, III, IV, V	Single-copy, serialized, Electronic Triplicate	1993 1988
Minnesota	2007	Electronic	C-II, III, IV, V		
Mississippi	2006	Electronic	C-II, III, IV, V		
Nevada	1995	Electronic	C-II, III, IV		

New Mexico	2005	Electronic	C-II, III, IV	Electronic, C-II only	1994-2000
New York	2005	Electronic/serialized security form	C-II, III, IV, V	Single-copy, serialized/ Electronic C-II & benzos Triplicate	1998 1972
North Carolina	2005	Electronic	C-II, III, IV, V		
North Dakota	2005	Electronic	C-II, III, IV, V		
Ohio	2005	Electronic	C-II, III, IV, V		
Oklahoma	1990	Electronic	C-II		
Pennsylvania	2006	Electronic	C-II, III, IV, V		
Rhode Island	1997	Electronic	C-II, III	Duplicate	1978
South Carolina	2006	Electronic	C-II, III, IV		
Tennessee	2002	Electronic	C-II, III, IV		
Texas*	2007	Electronic/serialized security form	C-II, III, IV, V	Single-copy, serialized/Electronic C-II only Triplicate	1997 1981
Utah	1995	Electronic	C-II, III, IV, V		
Vermont	2006	Electronic	C-II, III, IV		
Virginia	2006	Electronic	C-II, III, IV	Electronic (limited to SW region) C-II only	2002
Washington	2007	Electronic	C-II, III, IV, V		
West Virginia[a]	1995	Electronic	C-II, III, IV		
Wyoming	2003	Electronic	C-II, III, IV		

Notes:
(1) Current as of 06/13/2008; prescription monitoring programs are subject to change.
(2) Washington's previous program, utilizing triplicate prescriptions, was used for disciplinary purposes only and was not included.
* *Indicates physicians are required to obtain state-issued prescription forms.*
[a] The West Virginia program was discontinued in 1998, but re-authorized in 2002.

Sources: U.S. General Accounting Office, "Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion" May 2002; Drug Enforcement Administration, "Prescription Accountability Resource Guide," September 1998; and updated information obtained from states

References

Abrams FR. Colorado revised statutes in support of palliative care: Limiting criminal liability. *Journal of Palliative Medicine.* 2006;9:1254-1256.

Agency Medical Director's Group. *Interagency guideline on opioid dosing for chronic non-cancer pain*. October 12, 2006.

Alliance of States with Prescription Monitoring Programs. *The Goals of Prescription Monitoring*. Jamaica Plain, MA: Massachusetts Department of Health, Drug Control Program; 1999. http://www.nascsa.org/Alliance/PDF/Goals.PDF

Alliance of State Pain Initiatives. *Statement on State Prescription Monitoring Programs*. Madison, WI: AACPI; 2008. http://aspi.wisc.edu/documents/pdf/PMPStatement2008.pdf

American Academy of Pain Medicine, American Pain Society, American Society of Addiction Medicine. *Definitions Related to the Use of Opioids for the Treatment of Pain*. Glenview, IL: AAPM, APS, ASAM; 2001. http://www.ampainsoc.org/advocacy/opioids2.htm

American Alliance of Cancer Pain Initiatives. *Statement on Intractable Pain Treatment Acts (IPTA)*. Madison, WI: AACPI; 2004.

American Medical Association-House of Delegates. *Protection for Physicians Who Prescribe Pain Medication H-120.960*. Chicago, IL: American Medical Association; 2003.

American Pain Foundation. *APF position statement on Washington State Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain: An educational pilot to improve care and safety with opioid treatment*. 2007.

American Pain Society. *The Washington State Agency Medical Directors Group (AMDG) published guidelines on opioid dosing for chronic non-cancer pain*. September 19, 2007.

Arnold R, Berger A, Billings JA, et al. *Clinical Practice Guidelines for Quality Palliative Care*. Brooklyn, NY: National Consensus Project for Quality Palliative Care; 2004. http://www.guideline.gov/summary/pdf.aspx?doc_id=5058&stat=1&string=

Breitbart W, Passik S, McDonald MV, et al. Patient-related barriers to pain management in ambulatory AIDS patients. *Pain.* 1998; 76:9-16.

Brushwood DB. Maximizing the value of electronic prescription monitoring programs. *Journal of Law, Medicine & Ethics.* 2003; 31(1):41-54.

Burckhardt CS, Goldenberg D, Crofford L, et al. *Guideline for the Management of Fibromyalgia Syndrome Pain in Adults and Children. APS Clinical Practice Guidelines Series, No. 4*. Glenview, IL: American Pain Society; 2005.

Burton AW, Fanciullo GJ, Beasley RD, Fisch MJ. Chronic pain in the cancer survivor: A new frontier. *Pain Medicine.* 2007;8:189-197.

Cancer Pain Management Policy Review Group. *American Cancer Society Position Statement on Regulatory Barriers to Quality Cancer Pain Management*. National Government Relations Department, American Cancer Society; 2001a.

Cancer Pain Management Policy Review Group. *American Cancer Society Policy Statement on Cancer Pain Management*. National Government Relations Department, American Cancer Society; 2001b.

Cancer Pain Management Policy Review Group. *American Cancer Society Position Statement on Prescription Monitoring and Drug Utilization Review Programs*. National Government Relations Department, American Cancer Society; 2001c.

Cicero TJ, Inciardi JA, Munoz A. Trends in abuse of Oxycontin and other opioid analgesics in the United States: 2002-2004. *The Journal of Pain.* 2005; 6(10):662-672.

Cintron A, Morrison RS. Pain and ethnicity in the United States: A systematic review. *Journal of Palliative Medicine.* 2006;9:1454-1473.

Cleary JF. The pharmacologic management of cancer pain. *Journal of Palliative Medicine.* 2007;10:1369-1394.

Code of Federal Regulations. *Title 21 CFR §1306.04(a)*.
http://edocket.access.gpo.gov/cfr_2003/aprqtr/pdf/21cfr1306.04.pdf

Code of Federal Regulations. *Title 21 CFR §1306.07(c)*.
http://edocket.access.gpo.gov/cfr_2003/aprqtr/pdf/21cfr1306.07.pdf

Compton WM, Volkow ND. Major increases in opioid analgesic abuse in the United States: Concerns and strategies. *Drug and Alcohol Dependence.* 2006;81:103-107.

Connecticut Cancer Pain Initiative, American Cancer Society New England Division. *Connecticut Pain Summit: Promoting Proper Use of Opioid Analgesics, Report and Recommendations*. Meriden, CT: American Cancer Society New England Division; 2003.

Controlled Substances Act. *Title 21 USC §801(1)*. http://www.deadiversion.usdoj.gov/21cfr/21usc/801.htm

Controlled Substances Act. *Title 21 USC §823(a)(1)*.
http://www.deadiversion.usdoj.gov/21cfr/21usc/823.htm

Controlled Substances Act. *Title 21 USC §826(a)*. http://www.deadiversion.usdoj.gov/21cfr/21usc/826.htm

Controlled Substances Act. *Title 21 USC §902*. http://www.deadiversion.usdoj.gov/21cfr/21usc/902.htm

Council of Europe. *Recommendation (2003) 24 of the Committee of Ministers to Member States on the Organisation of Palliative Care*. Adopted by the Committee of Ministers at the 860th meeting of the Ministers' Deputies; 12 November 2003.
https://wcd.coe.int/ViewDoc.jsp?id=85719&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75

Dahl JL, Bennett ME, Bromley MD, Joranson DE. Success of the State Pain Initiatives. *Cancer Practice.* 2002; 10(Suppl. 1):S9-S13.

Dahl JL, Joranson DE. Relieving cancer pain. *World Health.* 1987; (November):28-29.

Drayer RA, Henderson J, Reidenberg M. Barriers to better pain control in hospitalized patients. *Journal of Pain and Symptom Management.* 1999; 17(6):434-440.

Drug Enforcement Administration. Issuance of multiple prescriptions for Schedule II controlled substances. Docket No. DEA-287F. *Federal Register*; 72[222]:64921-64930. November 19, 2007.
http://www.deadiversion.usdoj.gov/fed_regs/rules/2007/fr1119.htm

Drug Enforcement Administration. Issuance of multiple prescriptions for Schedule II controlled substances. Docket No. DEA-287N. *Federal Register*; 71[172]:52724-52726. September 6, 2006.
http://www.deadiversion.usdoj.gov/fed_regs/rules/2006/fr0906.htm

Drug Enforcement Administration. *Practitioner's manual: A guideline to the practitioner's responsibilities under the Controlled Substances Act of 1970*. Washington, DC: United States Department of Justice; 2006. http://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html

Drug Enforcement Administration. *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act of 1970*. Eighth ed. Washington, DC: U.S. Department of Justice; 2004. http://www.deadiversion.usdoj.gov/pubs/manuals/index.html

Drug Enforcement Administration, Last Acts, Pain & Policy Studies Group, et al. *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*. Washington, DC: Last Acts; 2001. http://www.painpolicy.wisc.edu/dea01.htm

Drug Enforcement Administration, National Alliance for Model State Drug Laws. *Diversion and Abuse of Prescription Drugs: A Closer Look at State Prescription Monitoring Programs*. Washington, DC: Drug Enforcement Administration; 2000.

Drug Enforcement Administration - Office of Diversion Control. *Prescription Accountability Resource Guide*. Washington, DC: Drug Enforcement Administration; 1998.

Dworkin RH, O'Connor AB, Backonja M et al. Pharmacologic management of neuropathic pain: Evidence-based recommendations. *Pain.* 2007;132:237-251.

Federal Food Drug and Cosmetic Act. *Title 21 USCS Chapter 9, §301 Et Seq*.

Federal Register. *37 FR 16503*. 1972.

Federal Register. *40 FR 15394*. 1975.

Federal Register. *48 FR 26733*. 1983.

Federal Register. *53 FR 50593*. 1988.

Federal Register. *69 FR 67170*. 2004.

Federal Register. *71 FR 14520*. 2006.

Federation of State Medical Boards of the United States Inc. *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Euless, TX: Federation of State Medical Boards of the United States Inc; 1998.

Federation of State Medical Boards of the United States Inc. *A Guide to the Essentials of a Modern Medical Practice Act*. 9th ed. Dallas, TX: Federation of State Medical Boards; 2000. http://www.fsmb.org/pdf/GPROL_essentials_eleventh_edition.pdf

Federation of State Medical Boards of the United States Inc. *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Dallas, TX: Federation of State Medical Boards of the United States Inc.; 2004. http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf

Fine PG, Fanciullo GJ, Miaskowski CA. *Clinical guidelines for the use of chronic opioid therapy for chronic noncancer pain*. In press.

Fine PG, Portenoy RK. *A clinical guide to opioid analgesia (2nd edition)*. Vendome Group, LLC; 2007.

Fishman SM. *Responsible opioid prescribing: A physician's guide*. Washington, DC: Waterford Life Sciences; 2007.

Fishman SM, Papazian JS, Riches PS, Gilson AM. Regulating opioid prescribing through prescription monitoring programs: Balancing drug diversion and treatment of pain. *Pain Medicine.* 2004; 5(3):309-324.

Foley KM, Back A, Bruera E, et al. Managing your symptoms. In: Foley KM, Back A, Bruera E, Coyle N, Loscalzo MJ, Shuster JL et al., eds. *When the Focus in on Care: Palliative Care and Cancer*. Atlanta, GA: American Cancer Society; 2005:157-191.

Food and Drug Administration. Use of approved drugs for unlabeled indications. *FDA Drug Bulletin.* 1982; 12(1):4-5.

Fujimoto D. Regulatory issues in pain management. *Clinics in Geriatric Medicine.* 2001; 17(3):537-551.

Furrow BR. Pain management and provider liability: No more excuses. *Journal of Law, Medicine & Ethics.* 2001; 29(1):28-51.

Furstenberg CT, Ahles TA, Whedon MB, et al. Knowledge and attitudes of health-care providers toward cancer pain management: a comparison of physicians, nurses, and pharmacists in the State of New Hampshire. *Journal of Pain and Symptom Management.* 1998; 15(6):335-349.

Gilson AM. Laws and policies affecting pain management. *Bonica's Management of Pain* (Fourth edition). In press.

Gilson AM. Interpreting changes in state laws and regulations governing the use of controlled substances to treat pain. *Advances in Pain Management.* 2007;1:60-66.

Gilson AM, Joranson DE. U.S. policies relevant to the prescribing of opioid analgesics for the treatment of pain in patients with addictive disease. *Clinical Journal of Pain.* 2002; 18(4 suppl):S91-S98. http://www.painpolicy.wisc.edu/publicat/02cjpn/Tx_addicts.pdf

Gilson AM, Joranson DE. The Federal Drug Enforcement Administration "prescription series" proposal: Continuing concerns. *Journal of Pain & Palliative Care Pharmacotherapy.* 2007;21(4):21-24. http://www.painpolicy.wisc.edu/publicat/07jppcp/agdj07.pdf

Gilson AM, Joranson DE. Is the Federal Drug Enforcement Administration's new "prescription series" regulation balanced? *Journal of Pain & Palliative Care Pharmacotherapy.* In press.

Gilson AM, Joranson DE, Maurer MA. Improving state medical board policies: Influence of a model. *Journal of Law, Medicine & Ethics.* 2003; 31(1):119-129. http://www.painpolicy.wisc.edu/publicat/03jlme/jlme_model.pdf

Gilson AM, Joranson DE, Maurer MA. Improving state pain policies: Recent progress and continuing opportunities. *CA: A Cancer Journal for Clinicians.* 2007;57:341-353. http://caonline.amcancersoc.org/cgi/reprint/57/6/341

Gilson AM, Joranson DE, Maurer MA, Ryan KM, Garthwaite JP. Progress to achieve balanced state policy relevant to pain management and palliative care: 2000-2003. *Journal of Pain and Palliative Care Pharmacotherapy.* 2005; 19(1):7-20. http://www.painpolicy.wisc.edu/publicat/05jppcp/05jppcp.pdf

Gilson AM, Maurer MA. Legal and regulatory considerations in pain management. *Principles of Addiction Medicine* (Fourth edition). In press.

Gilson AM, Maurer MA, Joranson DE. State policy affecting pain management: Recent improvements and the positive impact of regulatory health policies. *Health Policy.* 2005; 74(2):192-204. http://www.painpolicy.wisc.edu/publicat/05hlthpol/05hlthpol.pdf

Gilson AM, Ryan KM, Joranson DE, Dahl JL. A reassessment of trends in the medical use and abuse of opioid analgesics and implications for diversion control: 1997-2002. *Journal of Pain & Symptom Management.* 2004;28:176-188. http://www.painpolicy.wisc.edu/publicat/04jpsm/04jpsm.pdf

Heins A, Grammas M, Heins JK, Costello MW, Huang K, Mishra S. Determinants of variation in analgesic and opioid prescribing practice in an emergency department. *Journal of Opioid Management.* 2006;2:335-340.

Hill CS, Jr. The negative effect of regulatory agencies on adequate pain control. *Primary Care Cancer.* 1989; 11:47-51.

Hoffmann DE, Tarzian AJ. Achieving the right balance in oversight of physician opioid prescribing for pain: The role of state medical boards. *Journal of Law, Medicine & Ethics.* 2003; 31(1):21-40.

Hollen CJ, Hollen CW, Stolte K. Hospice and hospital oncology unit nurses: A comparative survey of knowledge and attitudes about cancer pain. *Oncology Nursing Forum.* 2000; 27(10):1593-1599.

Inciardi JA, Surratt HL, Kurtz SP, Cicero TJ. Mechanisms of prescription drug diversion among drug-involved club- and street-based populations. *Pain Medicine.* 2007;8:171-183.

Institute of Medicine Committee on Care at the End of Life. *Approaching Death: Improving Care at the End of Life*. Washington, DC: National Academy Press; 1997. http://books.nap.edu/catalog/5801.html

Institute of Medicine Committee on Cancer Control in Low- and Middle-Income Countries. *Cancer control opportunities in low- and middle-income countries*. Washington, DC: The National Academies Press; 2007.

Institute of Medicine Committee on Opportunities in Drug Abuse Research. *Pathways of Addiction: Opportunities in Drug Abuse Research*. Washington, DC: National Academy Press; 1996. http://www.nap.edu/catalog/5297.html

Institute of Medicine National Cancer Policy Board. *Improving Palliative Care for Cancer*. Foley KM, Gelband H, editors. Washington, DC: National Academy Press; 2001.

International Narcotics Control Board. *Report of the International Narcotics Control Board for 1989: Demand for and Supply of Opiates for Medical and Scientific Needs*. Vienna, Austria: United Nations; 1989.

International Narcotics Control Board. *Report of the International Narcotics Control Board for 1995: Availability of Opiates for Medical Needs*. New York, NY: United Nations; 1996. http://www.incb.org/pdf/e/ar/1995/suppl1en.pdf

International Narcotics Control Board. *Report of the International Narcotics Control Board for 2004*. New York, NY: United Nations; 2005. http://www.incb.org/incb/annual_report_2004.html

International Narcotics Control Board. *Report of the International Narcotics Control Board for 2006.* New York, NY: United Nations; 2007.

Johnson SH. Providing relief to those in pain: A retrospective on the scholarship and impact of the Mayday project. *Journal of Law, Medicine & Ethics.* 2003; 31(1):15-20.

Joranson DE. Federal and state regulation of opioids. *Journal of Pain and Symptom Management.* 1990a; 5(Suppl.)(1):S12-S23. http://www.painpolicy.wisc.edu/publicat/90jpsmf.htm

Joranson DE. A new drug law for the states: An opportunity to affirm the role of opioids in cancer pain relief. *Journal of Pain and Symptom Management.* 1990b; 5(5):333-336. http://www.painpolicy.wisc.edu/publicat/90jpsmn.htm

Joranson DE, Carrow GM, Ryan KM, et al. Pain management and prescription monitoring. *Journal of Pain and Symptom Management.* 2002; 23(3):231-238.
http://www.painpolicy.wisc.edu/publicat/02jpsm2/pmp.pdf

Joranson DE, Dahl JL. Achieving balance in drug policy: The Wisconsin model. In: Hill CS, Jr., Fields WS, eds. *Advances in pain research and therapy, volume 11*. New York: Raven Press; 1989:197-204.

Joranson DE, Gilson AM. Controlled substances, medical practice, and the law. In: Schwartz HI, ed. *Psychiatric Practice Under Fire: the Influence of Government, the Media, and Special Interests on Somatic Therapies*. 1st ed. Washington DC: American Psychiatric Press, Inc.; 1994:173-194.
http://www.painpolicy.wisc.edu/publicat/94appcs.htm

Joranson DE, Gilson AM. Improving pain management through policy making and education for medical regulators. *Journal of Law, Medicine & Ethics.* 1996; 24(4):344-347.
http://www.painpolicy.wisc.edu/publicat/96jlmei.htm

Joranson DE, Gilson AM. State intractable pain policy: Current status. *American Pain Society Bulletin.* 1997; 7(2):7-9. http://www.painpolicy.wisc.edu/publicat/97apssi.htm

Joranson DE, Gilson AM. Pharmacists' knowledge of and attitudes toward opioid pain medications in relation to federal and state policies. *Journal of the American Pharmaceutical Association.* 2001; 41(2):213-220. http://www.painpolicy.wisc.edu/publicat/01japhak/index.htm

Joranson DE, Gilson AM. Legal and regulatory issues in the management of pain. In: Graham AW, Schultz TK, Mayo-Smith MF, Ries RK, Wilford BB, eds. *Principles of Addiction Medicine*. Third ed. Chevy Chase, MD: American Society of Addiction Medicine, Inc.; 2003:1465-1474.

Joranson DE, Gilson AM. Drug crime is a source of abused pain medications in the United States [letter]. *Journal of Pain and Symptom Management.* 2005; 30(4):299-301.
http://www.sciencedirect.com/science?_ob=MImg&_imagekey=B6T8R-4HDPX61-1-1&_cdi=5093&_user=443835&_orig=browse&_coverDate=10%2F31%2F2005&_sk=999699995&view=c&wchp=dGLbVzb-zSkWz&md5=7d061305721e33d820fadb2e58fa4ce8&ie=/sdarticle.pdf

Joranson DE, Gilson AM. Wanted: A public health approach to prescription opioid abuse and diversion (Editorial). *Pharmacoepidemiology and Drug Safety.* 2006;15:632-634.
http://www.painpolicy.wisc.edu/publicat/pharmaco/commentary.pdf

Joranson DE, Gilson AM. A much-needed window on opioid diversion (Editorial). *Pain Medicine.* 2007;8:128-129. http://www.painpolicy.wisc.edu/publicat/07painmed/07painmed.pdf

Joranson DE, Gilson AM, Dahl JL, Haddox JD. Pain management, controlled substances, and state medical board policy: A decade of change. *Journal of Pain and Symptom Management.* 2002; 23(2):138-147.
http://www.painpolicy.wisc.edu/publicat/02jpsm1/index.htm

Joranson DE, Gilson AM, Nischik JA. North Carolina, pain management and end-of-life care: Communicating the policy. *Federation Bulletin, Journal of Medical Licensure & Discipline.* 2002; 88(3):116-119. http://www.painpolicy.wisc.edu/publicat/02fsmb/index.htm

Joranson DE, Gilson AM, Ryan KM, et al. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation*. Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center. Madison, WI; 2000.

Katz NP, McCarberg BH, Reisner L. *Managing chronic pain with opioids in primary care*. Wakefield: ApotheCom Associates, LLC; 2007.

Kutner JS, Kassner CT, Nowels DE. Symptom burden at the end of life: Hospice providers' perceptions. *Journal of Pain and Symptom Management.* 2001; 21(6):473-480.

Lazarus H, Neumann CJ. Assessing undertreatment of pain: the patients' perspectives. *Journal of Pharmaceutical Care in Pain and Symptom Control.* 2001; 9(4):5-34.

Lee LE. Medication in the control of pain in terminal cancer with reference to the study of newer synthetic analgesics. *Journal of the American Medical Association.* 1941; 116(3):216-220.

Lin JJ, Alfandre D, Moore C. Physician attitudes toward opioid prescribing for patients with persistent noncancer pain. *Clinical Journal of Pain.* 2007;23:799-803.

Martino AM. In search of a new ethic for treating patients with chronic pain: What can medical boards do? *Journal of Law, Medicine & Ethics.* 1998; 26(4):332-349.

Maryland State Advisory Council on Pain Management. *Final Report to the General Assembly*. Annapolis: Maryland State Advisory Council on Pain Management; 2004.

Maurer MA, Gilson AM, Joranson DE. Federal and state policies at the interface of pain and addiction. In: Smith H, Passik S, eds. *Pain and Chemical Dependency*. New York: Oxford University Press; 2008:377-83.

McCracken LM, Hoskins J, Eccleston C. Concerns about medication and medication use in chronic pain. *The Journal of Pain.* 2006;7:726-734.

McErlean M, Triner W, Young A. Impact of outside regulatory investigation on opiate administration in the Emergency Department. *The Journal of Pain.* 2006;7:947-950.

McMillan SC, Tittle M, Hagan S, Laughlin J, Tabler REJr. Knowledge and attitudes of nurses in veterans hospitals about pain management in patients with cancer. *Oncology Nursing Forum.* 2000; 27(9):1415-1423.

Merritt D, Fox-Grage W, Rothouse M, et al. *State Initiatives in End-of-Life Care: Policy Guide for State Legislators*. Washington, DC: National Conference of States Legislatures; 1998.

Miaskowski C, Cleary J, Burney R, et al. *Guideline for the Management of Cancer Pain in Adults and Children. APS Clinical Practice Guidelines Series, No. 3*. Glenview, IL: American Pain Society; 2005.

Michigan Department of Consumer & Industry Services. *Pain and Symptom Management Advisory Committee Report*. Lansing: Michigan Department of Consumer and Industry Services; 2002.

Morrison RS, Wallenstein S, Natale DK, Senzel RS, Huang L. "We don't carry that"--Failure of pharmacies in predominantly nonwhite neighborhoods to stock opioid analgesics. *New England Journal of Medicine.* 2000; 342(14):1023-1026.

National Alliance for Model State Drug Laws. *Model Prescription Monitoring Act*. Alexandria, VA: National Alliance for Model State Drug Laws; 2002.
http://www.namsdl.org/resources/v3a%20model%20prescription%20monitoring%20act.pdf

National Association of Attorneys General. *Improving End-of-Life Care: The Role of Attorneys General*. Edmondson WAD, editor. Washington, DC: National Association of Attorneys General; 2003a.
http://www.oag.state.ok.us/oagweb.nsf/0/7671c16b66cde508862572b400738e5f/$FILE/6-9end-of-life.pdf

National Association of Attorneys General. *Resolution Calling for a Balanced Approach to Promoting Pain Relief and Preventing Abuse of Pain Medications*. Adopted at the National Association of Attorneys General Spring Meeting; Washington, DC; March 17-20, 2003b.

National Association of State Controlled Substances Authorities. *NASCSA Resolution 99-01. A Resolution Endorsing the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted at the NASCSA 15th Annual Educational Conference; Coeur d'Alene, Idaho; October 29, 1999.

National Conference of Commissioners on Uniform State Laws. *Uniform Controlled Substances Act*. NCCUSL; Chicago, IL. Adopted at its Annual Conference Meeting in its Ninety-Ninth Year; Milwaukee, WI; July 13-20, 1990.

National Conference of Commissioners on Uniform State Laws. *Uniform Controlled Substances Act*. NCCUSL; Chicago, IL. Adopted at its Annual Conference Meeting in its One-Hundred-and-Third-Year; Chicago, IL; July 29-August 5, 1994.

National Institutes of Health. *State-of-the-Science Conference Statement: Improving End-of-Life Care*. Draft statement prepared following a National Institutes of Health State-of-the-Science Conference on Improving End-of-Life Care; Bethesda, MD; December 6-8, 2004. http://consensus.nih.gov/2004/2004EndOfLifeCareSOS024PDF.pdf

National Institutes of Health Consensus Development Program. *Symptom Management in Cancer: Pain, Depression and Fatigue*. Statement prepared following a National Institutes of Health State-of-the-Science Conference on Symptom Management in Cancer; Bethesda, MD; July 15-17, 2002. http://www.nlm.nih.gov/archive//20061214/pubs/cbm/cancersymptoms.pdf

New York State Public Health Council. *Breaking Down the Barriers to Effective Pain Management: Recommendations to Improve the Assessment and Treatment of Pain in New York State*. Albany, NY: New York State Department of Health; 1998.

Noah L. Challenges in the federal regulation of pain management technologies. *Journal of Law, Medicine & Ethics.* 2003; 31(1):55-74.

Novak S, Nemeth WC, Lawson KA. Trends in medical use and abuse of sustained-release opioid analgesics: A revisit. *Pain Medicine.* 2004;5:59-65.

Oregon Pain Management Commission. *Oregon Pain Management Commission position on the Washington state Interagency Guideline on opioid dosing for chronic non-cancer pain*. 2007.

Pain & Policy Studies Group. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (Second edition)*. University of Wisconsin Comprehensive Cancer Center. Madison, WI; 2003.

Pain & Policy Studies Group. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (Third edition)*. University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI; 2006.

Pain & Policy Studies Group. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (Fourth edition)*. University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI; 2007.

Pain & Policy Studies Group. *Achieving Balance in State Pain Policy: A Progress Report Card*. University of Wisconsin Comprehensive Cancer Center. Madison, WI; 2003.

Pain & Policy Studies Group. *Achieving Balance in State Pain Policy: A Progress Report Card (Second edition)*. University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI; 2006.

Pain & Policy Studies Group. *Achieving Balance in State Pain Policy: A Progress Report Card (Fourth edition)*. University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI; 2008.

Passik SD, Byers K, Kirsh KL. Empathy and the failure to treat pain. *Palliative and Supportive Care.* 2007;5:167-172.

Patton CV, Sawicki DS. *Basic Methods of Policy Analysis and Planning*. Second ed. Englewood Cliffs, NJ: Prentice Hall; 1993.

Paulozzi LJ, Budnitz DS, Xi Y. Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiology and Drug Safety.* 2006;15:618-627.

Peindl KS, Mannelli P, Wu L, Patkar AA. Trends in nonheroin opioid abuse admissions: 1992-2004. *Journal of Opioid Management.* 2007;3:215-223.

Peppin J. Washington state develops guideline for opioid dosing of chronic noncancer pain. *Pain Medicine Network.* 2008;23:3.

Pletcher MJ, Kertesz SG, Kohn MA, Gonzales R. Trends in opioid prescribing by race/ethnicity for patients seeking care in U.S. emergency departments. *JAMA.* 2008;299:70-78.

Portenoy RK, Sibirceva U, Smout R et al. Opioid use and survival at the end of life: A survey of a hospice population. *Journal of Pain & Symptom Management.* 2006;32:532-540.

Public Health and Welfare. *Title 42 USC §280g-3*.

Reidenberg M. *We Should Not Say 'Drug Safety' When We Mean 'Drug Toxicity'*. World Health Organization; Geneva, Switzerland.

Rhymes JA. Barriers to effective palliative care of terminal patients: An international perspective. *Clinics in Geriatric Medicine.* 1996; 12(2):407-416.

Rich BA. An ethical analysis of the barriers to effective pain management. *Cambridge Quarterly of Healthcare Ethics.* 2000; 9:54-70.

Rich BA. Overcoming legal barriers to competent and compassionate pain relief for the dying patient. *American Pain Society Bulletin.* 2005; 15(1):1, 6, 9.

Richard J, Reidenberg M. The risk of disciplinary action by state medical boards against physicians prescribing opioids. *Journal of Pain and Symptom Management.* 2005; 29(2):206-212.

Rolnick SJ, Jackson J, Nelson WW et al. Pain management in the last six months of life among women who died of ovarian cancer. *Journal of Pain & Symptom Management.* 2007;33:24-31.

Roth CS, Burgess DJ, Mahowald ML. Medical residents' beliefs and concerns about using opioids to treat chronic cancer and noncancer pain: A pilot study. *Journal of Rehabilitation Research & Development.* 2007;44:263-270.

Ross-Degnan D, Simoni-Wastila L, Brown JS, Mah M, Cosler LE. A controlled study of the effects of state surveillance on indicators of problematic and non-problematic benzodiazepine use in a medicaid population. *International Journal of Psychiatry in Medicine.* 2004; 34(2):103-123.

Savage SR, Joranson DE, Covington EC, et al. Definitions related to the medical use of opioids: Evolution towards universal agreement. *Journal of Pain and Symptom Management.* 2003; 26(1):655-667. http://www.painpolicy.wisc.edu/biblio.htm

Schwaderer KA, Itano JK. Bridging the healthcare divide with patient narvigation: Development of a research program to address disparities. *Clinical Journal of Oncology Nursing.* 2007;11:633-639.

Simon LS, Lipman AG, Caudill-Slosberg M, et al. *Guideline for the Management of Pain in Osteoarthritis, Rheumatoid Arthritis, and Juvenile Chronic Arthritis. APS Clinical Practice Guidelines Series, No. 2*. Glenview, IL: American Pain Society; 2002.

Simoni-Wastila L, Ross-Degnan D, Mah C, et al. A retrospective data analysis of the impact of the New York triplicate prescription program on benzodiazepine use in Medicaid patients with chronic psychiatric and neurologic disorders. *Clinical Therapeutics.* 2004; 26(2):322-336.

Simoni-Wastila L, Tompkins C. Balancing diversion control and medical necessity: The case of prescription drugs with abuse potential. *Substance Use & Misuse.* 2001; 36(9 & 10):1275-1296.

Strickland JM, Huskey A, Brushwood DB. Pharmacist-physician collaboration in pain management. *Journal of Opioid Management.* 2007;3:295-301.

Taylor AL, Gostin LO, Pagonis KA. Ensuring effective pain treatment. *JAMA.* 2008;299:89-91.

Thomson Healthcare. *Physicians' Desk Reference*. 58th ed. Montvale, NJ: Thomson PDR; 2004.

Tolle SW, Tilden VP, Rosenfeld AG, Hickman SE. Family reports of barriers to optimal care of the dying. *Nursing Research.* 2000; 49(6):310-317.

Tucker KL. Treatment of pain in dying patients (to the Editor). *New England Journal of Medicine.* 1998; 338(17):1231.

Tucker KL. Medical board corrective action with physicians who fail to provide adequate pain care. *Journal of Medical Licensure and Discipline.* 2001; 87(4):130-131.

Tucker KL. A piece of the puzzle: Bringing accountability to failure to treat pain adequately. *Journal of Palliative Medicine.* 2003; 6(4):615-617.

United Nations. *Single Convention on Narcotic Drugs, 1961, As Amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961*. New York, NY: United Nations; 1977. http://www.incb.org/pdf/e/conv/convention_1961_en.pdf

United Nations Economic and Social Council. *Treatment of Pain Using Opioid Analgesics; Resolution 2005-25*. Report on the forty-eighth session of the Commission on Narcotic Drugs E/2005/28; 19 March 2004 and 7-11 March 2005; issued 22 July 2005a. http://www.un.org/docs/ecosoc/documents/2005/resolutions/Resolution%202005-25.pdf

United Nations Economic and Social Council. *Demand for and Supply of Opiates Used to Meet Medical and Scientific Needs; Resolution 2005-26*. Report on the forty-eighth session of the Commission on Narcotic Drugs E/2005/28; 19 March 2004 and 7-11 March 2005; issued 22 July 2005b. http://www.un.org/docs/ecosoc/documents/2005/resolutions/Resolution%202005-26.pdf

United Nations General Assembly. *International Covenant on Economic, Social and Cultural Rights*. United Nations; New York, NY. Adopted at the 1496th U.N. General Assembly plenary meeting, 16 December 1966;

United States General Accounting Office. *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*. Washington, DC: United States General Accounting Office, GAO-02-634; 2002. http://www.gao.gov/new.items/d02634.pdf

United States General Accounting Office. *Prescription Drugs: State Monitoring Programs May Help to Reduce Illegal Diversion*. Washington, DC: United States General Accounting Office, GAO-04-524T; 2004. http://www.gao.gov/new.items/d04524t.pdf

United States v Evers. 643 F2d 1043 5th Circuit, 1981.

Von Roenn JH, Cleeland CS, Gonin R, Hatfield AK, Pandya KJ. Physician attitudes and practice in cancer pain management: A survey from the Eastern Cooperative Oncology Group. *Annals of Internal Medicine.* 1993; 119:121-126.

Wagner AK, Soumerai SB, Zhang F, et al. Effects of state surveillance on new post-hospitalization benzodiazepine use. *International Journal for Quality in Health Care.* 2003; 15(5):423-431.

Ward SE, Goldberg N, Miller-McCauley V et al. Patient-related barriers to management of cancer pain. *Pain.* 1993;52:319-324.

Wastila LJ, Bishop C. The influence of multiple copy prescription programs on analgesic utilization. *Journal of Pharmaceutical Care in Pain and Symptom Control.* 1996; 4(3):3-19.

Weiss SC, Emanuel LL, Fairclough DL, Emanuel EJ. Understanding the experience of pain in terminally ill patients. *Lancet.* 2001; 357:1311-1315.

Weissman DE, Haddox JD. Opioid pseudoaddiction--an iatrogenic syndrome. *Pain.* 1989; 36:363-366.

World Health Assembly. *Cancer Prevention and Control. WHA 58.22*. Geneva, Switzerland: World Health Organization; 2005. http://www.who.int/gb/ebwha/pdf_files/WHA58-REC1/english/A58_2005_REC1-en.pdf

World Health Organization. *WHO Expert Committee on Drugs Liable to Produce Addiction: Third Report (Technical Report Series 57)*. Geneva, Switzerland: World Health Organization; 1952.

World Health Organization. *WHO Expert Committee on Drug Dependence: Sixteenth Report*. Geneva, Switzerland: World Health Organization; 1969.

World Health Organization. *Cancer Pain Relief*. Geneva, Switzerland: World Health Organization; 1986.

World Health Organization. *Cancer Pain Relief and Palliative Care: Report of the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (Technical Report Series 804)*. Geneva, Switzerland: World Health Organization; 1990.

World Health Organization. *Cancer Pain Relief: With a Guide to Opioid Availability*. Second ed. Geneva, Switzerland: World Health Organization; 1996. http://whqlibdoc.who.int/publications/9241544821.pdf

World Health Organization. *Cancer Pain Relief and Palliative Care in Children*. Geneva, Switzerland: World Health Organization; 1998a.

World Health Organization. *The Use of Essential Drugs: Eighth Report of the WHO Expert Committee (Technical Report Series 882)*. Geneva, Switzerland: World Health Organization; 1998b.

World Health Organization. *Achieving Balance in National Opioids Control Policy: Guidelines for Assessment*. Geneva, Switzerland: World Health Organization; 2000. http://www.painpolicy.wisc.edu/publicat/00whoabi/00whoabi.htm

World Health Organization. *National Cancer Control Programmes: Policies and Managerial Guidelines*. Second ed. Geneva, Switzerland: World Health Organization; 2002. http://www.who.int/cancer/media/en/408.pdf

World Health Organization Executive Board. *Cancer Control: Report by the Secretariat. 114th Session. EB114/3*. Geneva, Switzerland: World Health Organization; 2004.

World Health Organization. *WHO expert committee on drug dependence: thirty-fourth report*. Geneva, Switzerland: World Health Organization; 2006.

World Health Organization HIV-AIDS. *Palliative Care*. Geneva, Switzerland: World Health Organization; 2004.

Zacny J, Bigelow G, Compton P, Foley K, Iguchi M, Sannerud C. College on Problems of Drug Dependence taskforce on prescription opioid non-medical use and abuse: Position statement. *Drug Alcohol Depend.* 2003;69:215-232.