

Special Committee on Questionable and Deceptive Health Care Practices

Federation of State Medical Boards of the United States, Inc.

Note: Originally, this report was produced by the Special Committee on Health Care Fraud. At the Federation's 1999 House of Delegates meeting, the committee was renamed the Special Committee on Questionable and Deceptive Health Care Practices.

The Federation of State Medical Boards' governing body accepted this Report as policy in April 1997.

Section I: Preamble

In April 1995, Federation President Robert E. Porter, MD, established a special committee on health care fraud. The need for such a committee arose from the proliferation of unconventional and unproven medical practices and promotions in the United States, some of which may be questionable and thereby pose a risk to public health, safety and welfare. Recent national and state legislative initiatives prompted further concern because they could result in restricting state medical boards' ability to provide appropriate regulation of such practices. The committee was directed to research, review and evaluate questionable health care treatments, procedures and promotions which may be worthless and, therefore, deceptive and/or pose a risk to public health, safety and welfare. The committee was also charged with developing strategies which could be recommended to state medical boards for the regulation and discipline of physicians who engage in unsafe, worthless and/or deceptive practices.

The committee met several times since its inception and developed recommendations designed to assist state medical boards in evaluating, investigating and prosecuting physicians engaged in such practices. The committee limited its review to those practices, procedures and/or promotions which may be offered by allopathic or osteopathic physicians and, therefore, subject to medical boards' jurisdiction and are not widely taught in medical schools nor generally available in hospitals. Additionally, the committee has expanded its charge to include an educational component to develop recommendations for state medical boards in educating licensees, consumers and legislators on issues regarding unconventional and/or unproven health care treatments, procedures and promotions.

The committee recognized that the primary responsibility of state medical boards is to protect the public from the incompetent, unprofessional, improper and unlawful practice of medicine and, further, that the authority for state medical boards to regulate medical practice is determined by each state's medical practice act. In its capacity as a resource for research, policy development, education and information, the Federation has developed a model medical practice act (A Guide to the Essentials of a Modern Medical Practice Act) to assist state medical boards in developing legislative language necessary to effect regulation of medical practice.

Accordingly, the committee's initial recommendations included a proposal to revise pertinent sections of A Guide to the Essentials of a Modern Medical Practice Act in order to strengthen the ability of state medical boards to regulate fraudulent behavior. These recommendations were adopted by the Federation's House of Delegates during its April 1996 meeting and have been incorporated in the policy document. The revisions expand the responsibilities of the medical board to include protection against the fraudulent and/or deceptive practice of medicine and render the unlicensed practice of medicine a felonious offense.

The following objectives were identified by the committee.

- To develop recommendations to assist state medical boards in identifying, evaluating, investigating and prosecuting cases involving questionable health care practices.
- To develop strategies to monitor legislative initiatives supporting increased access to unconventional and unproven treatments and assist state medical boards in responding to such initiatives in the interest of public health, safety and welfare.
- To solicit support for the Federation's efforts to control health care fraud from medical professional organizations, governmental agencies and other interested organizations.
- To develop and implement educational opportunities for state medical board members, executive directors and investigative staff on effective regulation of questionable health care practices.

The recommendations contained in this final report of the Special Committee on Health Care Fraud are designed to achieve the above objectives.

Section II: Definitions

The committee recognizes the practice of medicine (defined in A Guide to the Essentials of a Modern Medical Practice Act) as

- advertising, holding out to the public or representing in any manner that one is authorized to practice medicine in the jurisdiction;
- offering or undertaking to prescribe, order, give or administer any drug or medicine for the use of any other person;
- offering or undertaking to prevent or to diagnose, correct and/or treat in any manner or by any means, methods, devices or instrumentalities any disease, illness, pain, wound, fracture, infirmity, defect or abnormal physical or mental condition of any person, including the management of pregnancy and parturition;
- offering or undertaking to perform any surgical operation upon any person; and
- using the designation Doctor, Doctor of Medicine, Doctor of Osteopathy, Physician, Surgeon, Physician and Surgeon, Dr., MD, DO or any combination thereof in the conduct of any occupation or profession pertaining to the prevention, diagnosis or treatment of human disease or condition unless such a designation additionally contains the description of another branch of the healing arts for which one holds a valid license in the jurisdiction.

Additionally, for the purposes of this report, the terms "alternative medicine/therapy" and/or "complementary medicine" have not been utilized by the committee due to a lack of consensus among both practitioners and the public as to their meaning. The committee has chosen to use the term "questionable health care practices" to include those treatments, procedures and/or promotions, conventional or unconventional, which may be unsafe and thereby considered a risk to the public's health, safety and welfare and/or which may be worthless and thereby likely to deceive or defraud the public.

Section III: Identification

Recommendation One: State medical boards should develop mechanisms to identify physicians who may be engaging in questionable health care practices.

In order to offer reasonable protection to the public, state medical boards must be able to identify physicians who engage in questionable health care practices which may endanger the public, either directly or indirectly. Direct harm may result in adverse patient outcomes and indirect harm may result in delay of appropriate diagnoses and/or treatments.

The committee suggests the following mechanisms to facilitate the identification of physicians engaging in questionable health care practices.

- Encourage consumer/patient reporting by increasing awareness among the public through distribution of educational materials and utilizing media sources.
- Encourage and expand reporting from licensees and other health care professionals by increasing awareness of reporting requirements through newsletters, announcements, alerts, advisory opinions and collaboration with state and local medical professional organizations and societies.
- Expand liaison efforts with regulatory agencies (federal, state and local), including the Federal Trade Commission, other state licensing authorities, state attorneys general, district attorneys and public health departments.
- Improve reporting from third party payers and peer review organizations (PROs).
- Periodically monitor health care promotional materials, including random review of newspapers, periodicals and other advertising mediums.

Section IV: Evaluation and Investigation

Recommendation Two: State medical boards should develop criteria for evaluating any health care practice which has been called into question.

In order to effectively process a complaint or report involving questionable health care practices, state medical boards must determine whether the practice in question is (1) indicated, (2) appropriate and (3) reasonably safe as compared to established treatment models. The committee strongly supports the concept that the prevailing standard of care used in evaluating health care practices be consistent, whether such treatment is regarded as "conventional" or "unconventional." Such standards include appropriate documentation, informed consent, appropriate monitoring and follow-up, rationale for treatment and periodic review of efficacy of treatment.

The committee suggests the following criteria be utilized in evaluating health care practices.

- Has an adequate patient assessment been conducted, including history and physical examination, laboratory studies, x-rays and other evaluative measures, to determine that the patient has the condition for which the treatment is being prescribed?
- Is the methodology promoted for diagnosis as reliable as other available methods of diagnosis?
- Is the risk/benefit ratio greater or less than that for other treatments for the same condition?
- Is it based upon competent and reliable scientific evidence, including properly conducted clinical trials, and/or is it supported by a scientific rationale?
- Is there logical and reasonable expectation that the treatment offered will result in a favorable patient outcome?
- Is the practitioner excessively compensated for the service provided?
- Are the practitioner's promotional claims supported by competent and reliable scientific evidence?
- Is the benefit achieved greater than that which can be expected by placebo alone?
- Has the patient's informed consent been adequately documented in the medical record?

Recommendation Three: State medical boards should utilize reliable information resources in their evaluation of questionable health care practices.

Reliable information may be obtained by utilizing databases such as Medline, NEXIS/LEXIS or Westlaw by searching the (1) name of the practice/therapy/treatment/promotion, (2) provider and/or promoter and (3) organizations involved in the promotion of such practice/therapy/treatment.

The committee suggests state medical boards query the following organizations to provide reliable information regarding specific questionable health care practices:

- Federation of State Medical Boards Library Services, 400 Fuller Wiser Road, Suite 300, Euless, Texas 76039; (817) 868-4000; Fax (817) 868-4099;

- National Council Against Health Fraud (NCAHF), PO Box 1276, Loma Linda, California 92354; Fax (909) 824-4848;
- Consumer Health Information Research Institute (CHIRI), 300 East Pink Hill Road, Independence, Missouri 64057; (816) 228-4595; Fax (816) 228-4995;
- Food and Drug Administration, Office of Health Affairs; 5600 Fishers Lane, HFY-1, Rockville, Maryland 20857; (301) 443-6143;
- Federal Trade Commission, Division of Service Industry Practices, Washington, DC 20580; (202) 326-3291; Fax (202) 326-3392; and
- Office of Alternative Medicine, National Institutes of Health, 6120 Executive Boulevard, EPS, Suite 450, Rockville, Maryland 20892; (301) 402-2466; Fax (301) 402-4741.

The committee suggests state medical boards obtain reference materials such as the following to provide a foundation for research into questionable health care practices.

- Reader's Guide to Alternative Health Methods, Zwicky, John F., PhD; Hafner, Arthur W., PhD; Barrett, Stephen, MD; and Jarvis, William T., MD. American Medical Association 1993.
- Alternative Medicine: What Works, Fugh-Berman, Adriane, MD. Odonian Press, 1996.
- The Vitamin Pushers: How the "Health Food" Industry is Selling America A Bill of Goods, Stephen Barrett, MD, and Victor Herbert, MD, JD, 1994. NY: Prometheus Press.
- The Health Robbers: A Close Look at Quackery in America, edited by Stephen Barrett, MD, and William T. Jarvis, PhD. Foreword by Ann Landers, 1993. NY: Prometheus Press.
- HealthSmarts, John H. Renner, MD. 1990, Health Facts Publishing, 300 E. Pink Hill Road, Independence, Missouri 64057-3220.
- The Honest Herbal, 3rd Edition, Varro E. Tyler, PhD. 1993, Pharmaceutical Products Press, Division of The Haworth Press, Inc., 10 Alice St., Binghamton, NY 13904-1580.
- Examining Holistic Medicine, edited by Douglas Stalker, PhD, and Clark Glymour, PhD. 1985, Prometheus Press, NY.

Recommendation Four: State medical boards' ancillary staff, including board investigators, should utilize methods to effectively investigate questionable health care practices.

State medical boards must rely heavily on their investigative staff to aggressively develop and present evidence that is thorough, cohesive, sequential and well-documented. It is necessary for investigators to remain abreast of trends in and promotions of questionable health care practices within the jurisdiction of the agency.

The committee suggests the following guidelines be implemented during the investigative stage.

- Select a reliable expert, familiar with the practice in question and willing to assist in the investigative stage.
- Gather evidence to include (1) promotional and other materials used to produce patient consent, (2) drug samples or medical devices together with manufacturer's package inserts and specifications, (3) proponent literature describing the practice in question together with medical/scientific justification and (4) competent and reliable scientific evidence on the efficacy/safety of the practice.
- Conduct a thorough review of the Medical Practice Act to determine all applicable breaches to be included in the board's complaint.

Section V: Disciplinary Action/Disposition

Recommendation Five: State medical boards should work in conjunction with state prosecutors in the initiation, development and disposition of cases involving questionable health care practices.

It is necessary to employ procedures to effectively present cases in the disciplinary process. The committee identified elements that are commonly utilized by respondents in cases involving questionable health care practices, specifically the use of testimonials and anecdotal evidence. Proponents of questionable health care practices likely hold strong views and convictions regarding the therapeutic approach and may have a large cadre of devotees, willing to testify on the respondent's behalf.

In order to successfully prosecute such cases, it is imperative that state attorneys be familiar with medical practice and terminology and be able to apply and argue case law and rules of evidence in terms of generally accepted scientific standards so that unreliable evidence may be excluded and not used by respondents in defense of prosecution. Following a determination by the state medical board to prosecute a complaint, the committee suggests the following elements be utilized in the disposition of cases involving questionable health care practices.

- Conduct thorough prehearing discovery to obtain additional information and the names and qualifications of defense expert witnesses.
- Conduct careful research of defense experts and their writings.
- Request a prehearing conference or evidentiary hearing to suppress unreliable evidence and exclude testimony of unqualified proponents testifying on behalf of the respondent as unreliable and inadmissible. Review *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993) and relevant state law to establish legal precedent on admissibility of disputed scientific evidence.
- Strategize trial presentation to not only prove the board's case, but to disprove the proponent of the practice in question.
- Utilize expert witnesses who can not only establish the board's case but also who can provide credible rebuttal of the evidence in support of the practice in question.

Recommendation Six: State medical boards should carefully evaluate all avenues of potential prosecution and coordinate such with appropriate federal, state and local agencies.

Certain breaches of the medical practice act may be subject to civil action or criminal prosecution in other forums. These breaches may include (1) the unlicensed practice of medicine, (2) deceptive advertising, (3) violations regarding controlled substances and/or (4) fraudulent billing practices.

The committee suggests that state medical boards coordinate with and among the following agencies in their respective potential areas of prosecutorial concern(s):

- Federal Trade Commission (deceptive/fraudulent health care promotions/claims);
- State Attorney General (consumer complaints/protection and deceptive/fraudulent health care promotions/claims);
- State Insurance Board/Commission (billing practices);
- Health Care Financing Administration (Medicare claims);
- U.S. Postal Service (mail fraud);
- U.S. Customs Service (import of unapproved/illicit drugs/devices);
- Food and Drug Administration (unapproved drugs/devices); and
- District Attorney (unlicensed practice of medicine and related criminal offenses).

Section VI: Legislative Strategies

Recommendation Seven: State medical boards should review their Medical Practice Acts and pursue legislative support for revisions to strengthen the medical board's ability to regulate physicians engaging in questionable health care practices.

There are increasing political and social pressures to provide the public with access to unconventional medical treatments, as evidenced by various recent federal and state legislative proposals. The committee

believes that there may be substantial direct and indirect harm to patients resulting from enactment of such legislation unless appropriate safeguards are included. In order to fulfill state medical boards' responsibility to protect the public from incompetent, unprofessional, improper, unlawful, fraudulent and/or deceptive medical practice, it is necessary for state medical boards to maintain legislative authority adequate to regulate all practices constituting the practice of medicine.

The committee suggests the following elements be included in all state Medical Practice Acts.

- The unlicensed practice of medicine should be deemed a felonious offense.
- State medical boards should be granted authority to use injunctive powers to order physicians and others engaged in questionable health care practices to immediately cease such practice pending hearing.
- State medical boards should be granted authority to monitor physicians engaged in questionable health care practices, including, but not limited to, requirements that physicians: (1) file treatment plans with the board, (2) report patient outcomes and (3) file periodic reports regarding the efficacy of treatment.

Recommendation Eight: State medical boards should notify the Federation of State Medical Boards of any state legislative initiatives identified that could diminish state medical board's ability to regulate questionable health care practices.

The committee suggests that the following mechanisms be implemented for monitoring and opposing such legislative measures.

- Request assistance from the Legislative Services Department of the Federation of State Medical Boards in analyzing and developing strategies in opposition to such state legislative measures.
- Identify individuals within the state willing to educate state legislators and legislative staff on the potential effects of such legislative initiatives.
- Assist legislators in soliciting written comments from the Food and Drug Administration and the Federal Trade Commission on the potential consumer health and economic effects of such legislative initiatives (requests are honored only if submitted by legislator).

Recommendation Nine: The Federation of State Medical Boards should monitor federal and state legislative activities regarding health freedom issues and develop strategies to assure that the authority of state medical boards is maintained.

Through its Legislative Services Department and government relations firm, the Federation monitors federal legislative initiatives to identify proposals that could impact state medical boards. Upon the identification of such measures, the Federation develops strategies to intervene and oppose measures that could negatively affect state medical boards. The committee supports and encourages the Federation in its legislative efforts to protect the authority of state medical boards to regulate the practice of medicine, both conventional and unconventional.

Section VI: Education

Recommendation Ten: State medical boards, with the assistance of the Federation of State Medical Boards, should develop educational opportunities for licensees regarding the prevalence, risks and efficacy of questionable health care practices.

In order to contain the proliferation of questionable health care practices, it is necessary to increase awareness among licensees. State medical boards may wish to develop educational programs in cooperation with state and local medical professional societies, organizations and hospital medical staff organizations. The committee supports and encourages education of medical board members and staff,

legislators and consumers. The committee also supports the Federation of State Medical Boards in its continuing development of educational programs through forums such as the Annual Meeting, workshops and publications as well the dissemination of timely information to its member boards on related issues via the FSMB computer network.

The committee suggests state medical boards use the following methods in developing educational opportunities for their licensees and publics.

- Present educational information at meetings of state and local medical professional societies and associations and other organized physician educational forums.
- Include educational information in board newsletters and other communications with licensees.
- Utilize media sources, public service announcements, consumer advocacy groups and other means to disseminate information to the public.

Section VII: Collaboration

Recommendation Eleven: On behalf of state medical boards, the Federation of State Medical Boards should collaborate with other agencies and organizations in efforts to identify and eliminate questionable health care practices that are adverse to the public health, safety and welfare.

The committee recognizes that the scope of this issue reaches far beyond the jurisdiction of state medical boards and, therefore, strongly encourages that a network of cooperation and collaboration be established to coordinate efforts to stop the spread of questionable health care practices.

The committee suggests the following forums for collaboration.

- Explore opportunities for mutual cooperation, including information sharing and education, with the American Medical Association and the American Osteopathic Association.
- Develop working relationships with other interested organizations, including, but not limited to, the National Association of Attorneys General, the National Conference of State Legislatures, American Legislative Exchange Conference, the Food and Drug Administration and the Federal Trade Commission in promoting responsible medical practices.

Section VIII: Conclusion

It has been estimated that up to \$100 billion is lost to health care fraud in the United States annually.¹ Medical interventions that do not conform to prevailing scientific standards are becoming increasingly popular. It is estimated that in 1990, Americans made 425 million visits to providers of "unconventional" medicine, exceeding the number of visits to all U.S. primary care physicians, at a cost of approximately \$13.7 billion.² It may be recognized that some alternative therapies may be beneficial and therefore warrant further investigation and possible integration into mainstream medical practice. However, because of the lack of reliable scientific evidence and clinical validation, safety has not been established for most of these modalities.

Questionable health care practices can pose significant risks to the public safety, either by causing direct patient harm, or indirectly by being needlessly expensive, delaying a more effective treatment or from being administered in an incompetent manner. This proliferation of questionable health care practices and promotions will continue if left unchecked and unregulated. State medical boards are charged with protecting the public from the unprofessional, improper, incompetent, unlawful, fraudulent and deceptive practice of medicine¹ and, therefore, state medical boards must assure that physicians practice responsible medicine.

Section IX: References

1. Stern, 1994.

2. Eisenberg et al, 1993.

3. A Guide to the Essentials of a Modern Medical Practice Act, Section I.