legal capacity under the applicable State law to apply for and obtain such diagnosis, counselling, administration of medication, or other services as actually are or were provided to him by the program with respect to which he is or was a patient, any consent required for disclosure under this part may be given only by the patient, notwithstanding the fact that the patient may be a minor.

(d) *Initial contacts.* When a minor applies for services under circumstances other than those described in paragraph (c) of this section, the fact of such application may not be disclosed, except as an incident to a communication authorized under paragraph (f) of this section, without consent of the applicant, to the applicant's parent, guardian, or other person authorized under State law to act on behalf of the applicant. When such an applicant refuses consent, it must be explained to the applicant that while he or she has the right (subject to the provisions of paragraph (f) of this section) to withhold such consent, the services applied for cannot be provided without it.

(e) *Collection or attempted collection of payment for services.* Where State law authorizes the furnishing of services to a minor without the consent of the minor's parent or guardian, no inquiry may be made of the parent's or guardian's financial responsibility, and no bill, statement, request for payment, or any other communication in respect of such services may be transmitted directly or indirectly to such parent or guardian, without the express written consent of the patient. Such consent may not be made a condition of the furnishing of services except in the case of a program which is not required by law, and does not in fact hold itself out as willing, to furnish services irrespective of ability to pay.

(f) *Applicant lacking capacity for rational choice:* When, in the judgment of a program director a minor applicant for services, because of extreme youth or mental or physical condition, lacks the capacity to make a rational decision on whether to consent to the notification of a parent or guardian, and the situation of the applicant poses a substantial threat to the life or physical well being of the applicant or any other individual, and such threat might be reduced by communicating the relevant facts to a parent or guardian of the applicant, such facts may be so communicated by the program director or by program personnel authorized by the director to do so.

§ 2.15–1 Minor patients.—Basis and purpose.

(a) The statutes authorizing this part are totally silent on the issue of the capacity of a minor to give consent for disclosures, and there is nothing in the legislative history to suggest that the question was ever considered by Congress. The question is, however, one which arises repeatedly, and it is therefore appropriately addressed under the general rulemaking authority conferred by subsection (g) of the authorizing legislation.

(b) Perhaps no legal issues are more highly charged than those affecting the relationship of parent and child. Since Congress has not evidenced an intention to affect this relationship, it is clear that local law should govern, and the task of rulemaking is limited to that of insuring, as far as possible, that the results under Federal law are consistent with local policy.

(c) Where a State has authorized the furnishing of treatment or other services of a given type to a minor without notice to or consent by the parent or guardian, it seems clear that a consistent Federal policy with respect to disclosure requires that consent for any disclosure of the treatment record be given by the minor. This policy, moreover, should not be frustrated by attempts to enforce parental financial responsibility in a situation where the State itself has determined that the minor should have a right to obtain services without involving the parent.

(d) A much more difficult problem is presented in the case of a minor who applies for services in a jurisdiction which has not determined that a minor should have the right to obtain them without parental knowledge or consent. The question may arise as to whether the clinician has an ethical or legal duty to notify the parent which conflicts with a duty of nondisclosure. The rules in § 2.15 are based upon the theory that Federal law should not invalidate a State policy which prohibits treatment without parental consent, but that keeping confidential a mere application for treatment is not ordinarily a sufficient transgression of such a State policy as to require an exception to the general Federal policy prohibiting disclosure of an application for services without the consent of the applicant.

(e) Section 2.15(f) deals with the case of the minor applicant who lacks the capacity to make a rational choice about consenting to disclosure. It is based upon the theory that where a person is actually as well as legally incapable of acting in his own interest, disclosures to a person who is legally responsible for him may be made to the extent that the best interests of the patient clearly so require. Any other rule could subject clinicians to an intolerable choice between violating the provisions of this part on the one hand, or failing to take action to avoid a preventable tragedy involving a minor, on the other. The statutes authorizing this part should not be read as requiring such a choice.

§ 2.16 Incompetent and deceased patients.—Rules.

(a) *Incompetent patients other than minors.* Where consent is required for any disclosure under this part, such consent in the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs may be given by the guardian or other person authorized under State law to act in the patient's behalf.

(b) *Deceased patients.*

(1) *In general.* Except as provided in paragraph (b)(2) of this section, where consent is required for any disclosure of this part, such consent in the case of records of a deceased patient may be given by an executor, administrator, or other personal representative. If there is no appointment of a personal representative, such consent may be given by the patient's spouse, or if none, by any responsible member of the patient's family.

(2) *Vital statistics.* In the case of a deceased patient, disclosures required under Federal or State laws involving the collection of death and other vital statistics may be made without consent.

§ 2.16–1 Incompetent and deceased patients.—Basis and purpose.

Section 2.16 essentially repeats the substance of § 1401.04 of the previous regulations, broadened to reflect the fact that the statutes now allow any consensual disclosures permitted by the regulations, and to cover the situation of deceased patients for whom no formal appointment of an executor, administrator, or other personal representative has been made. Written comments were received to the effect that the power to consent to disclosure in the case of a deceased patient should be limited to a personal representative. The expense of probate or administration in some jurisdictions could cause financial hardship to survivors, and on balance it is believed that where the assets of an estate are insufficient to justify the appointment of a personal representative, the public interest is served by permitting others to consent to disclosure.

§ 2.17 Security precautions.—Rules.

(a) *Precautions required.* Appropriate precautions must be taken for the security of records to which this part applies. Records containing any information pertaining to patients shall be kept in a secure room, or in a locked file cabinet, safe, or other similar container, when not in use.

(b) *Policies and procedures.* Depending upon the type and size of the program, appropriate policies and procedures should be instituted for the further security of records. For example, except where this function is personally performed by the program director, a single member of the program staff should be designated to process inquiries and requests for patient information, and a written procedure should be in effect regulating and controlling access by those members of the staff whose responsibilities require such access, and providing for accountability.

§ 2.17–1 Security precautions.—Basis and purpose.

The enormous variations in both the size and the type of programs to which this part is applicable preclude the formulation of specific requirements with respect to the physical security of records. Almost any requirement which could be laid down would, under some circumstances, either be impracticable or

perverse in its effects. For example, in a facility handling a variety of medical records, all of which are confidential and so marked, a requirement that those pertaining to drug or alcohol treatment be marked in any distinctive way would merely serve to identify such records as pertaining to drug or alcohol treatment—precisely the opposite of the intended result. The purpose of § 2.17, which is based upon § 1401.25 of the previous regulations, is to alert programs to the necessity of exercising due care with respect to the security of patient records.

§ 2.18 Extent of disclosure.—Rule.

Any disclosure made under this part, whether with or without the patient's consent, shall be limited to information necessary in the light of the need or purpose for the disclosure.

§ 2.18–1 Extent of disclosure.—Basis and purpose.

(a) Section 2.18 expresses the general principle, which has application in many different contexts, that any disclosure from records covered by this part should be limited to information necessary in the light of the need or purpose for the disclosure. It is identical to § 1401.06 of the previous regulations.

(b) This section should not be misunderstood as imposing a limitation on the scope of records which may or should be made available to health agencies conducting inspections as described in § 2.55. All of the records maintained by a program may be relevant to such inspection. The Congress has determined that disclosure under such circumstances is not a violation of the statutes authorizing this part; where such disclosure is required by Federal or State law, and the inspecting agency is a qualified State health agency as defined in § 2.55(e)(1), it becomes the responsibility of that agency to protect the confidentiality of information it acquires in the course of its lawful activities.

§ 2.19 Undercover agents and informants.—Rules.

(a) *Definitions.* As used in this section, § 2.19–1, and §§ 2.67 and 2.67–1,—

(1) The term "undercover agent" means a member of any Federal, State, or local law enforcement or investigative agency whose identity as such is concealed from either the patients or personnel of a program in which he enrolls or attempts to enroll.

(2) The term "informant" means a person who, at the request of a Federal, State, or local law enforcement or investigative agency or officer, carries on observation of one or more persons enrolled in or employed by a program in which he is enrolled or employed, for the purpose of reporting to such agency or officer information concerning such persons which he obtains as a result of such observation subsequent to such request.

(b) *General prohibition.* Except as otherwise provided in paragraph (c) of this section, or as specifically authorized by a court order granted under § 2.67,—

(1) No undercover agent or informant may be employed by or enrolled in any alcohol or drug abuse treatment program;

(2) No supervisor or other person having authority over an undercover agent may knowingly permit such agent to be or remain employed by or enrolled in any such program; and

(3) No law enforcement or investigative officer may recruit or retain an informant with respect to such a program.

(c) *Exceptions.* The enrollment of a law enforcement officer in a treatment program shall not be deemed a violation of this section if (1) such enrollment is solely for the purpose of enabling the officer to obtain treatment for his own abuse of alcohol or drugs, and (2) his status as a law enforcement officer is known to the program director.

§ 2.19–1 Undercover agents and informants.—Basis and purpose.

(a) In many instances, persons who are patients in treatment programs are making their first tentative efforts toward re-integration into productive society. They may be both vulnerable and suspicious, and the presence in a treatment program of undercover law enforcement agents or informants can have a devastating effect on the program's morale and therapeutic effectiveness. Moreover, it would appear that the purpose of such agents or informants may be to obtain precisely the type of personal information which might be revealed by inspection of counselor notes and other patient records maintained by the program. Thus, the placing of an undercover agent or informant in a program, either as a patient or as an employee, would appear to be contrary to the purposes for which the provisions of law authorizing this part were enacted, and properly subject to prohibition under regulations expressly authorized to carry out those purposes.

(b) From a policy standpoint, § 2.19 is based on the reasoning that while the use of undercover agents and informants in treatment programs is ordinarily to be avoided, there may occasionally arise circumstances where their use may be justified. Accordingly, where a showing is made in an application for an order under § 2.67 that the criteria set forth in that section are satisfied, the court may grant such an order.

(c) When this section of the regulations was proposed, numerous written comments were received urging that there be an absolute prohibition on the use of undercover agents and informants, and most of the witnesses at the hearings who addressed the issue at all testified to the same effect. A number of comments were received to the effect that § 2.19 should be dropped altogether, but this request was always clearly and often explicitly predicated on the assumption that failure to say anything about undercover agents and informants would make their use illegal. Our view is to the contrary: we think that the statutes, standing alone, do not prohibit the practice, and thus that in the absence of a specific prohibition in these regulations, the use of undercover agents and informants in treatment programs would not be unlawful. Since this is a view which we believe to be shared by the law enforcement and investigative agencies which are affected by § 2.19, there is as a practical matter no alternative to predicating these regulations upon its correctness.

(d) However desirable it may be, to limit the use of undercover agents and informants in treatment programs, we think a strong argument can be made against our power to impose an absolute prohibition. To the extent that the practice is susceptible to regulation through the rulemaking process at all, it is on the theory that it opens the way to disclosure of information which is or should be in program records, and thus is contrary to the purposes of the statutes. Since subsection (g) of the statutes confers express rulemaking authority to carry out these purposes, regulation of the use of undercover agents and informants is a proper subject for the exercise of that authority. But even the express statutory prohibition against direct disclosure of the content of patient records is subject to the power of the courts to authorize such disclosure under subsection (b)(2)(C) of the statutes. It seems difficult to argue that Congress intended to confer on rulemaking agencies the authority to impose an absolute prohibition even though its own restrictions (other than those on disclosures of patient identities from secondary records) are subject to being set aside by court order in particular cases. Since we have not attempted to exercise such an authority, it is not necessary to decide at this time whether it was conferred.

(e) A careful reading of the definitions set forth in § 2.19(a) is crucial to an understanding of the prohibitions which are imposed by § 2.19. Objections to the section were made informally but vigorously on behalf of the Drug Enforcement Administration, on the ground that the testimony of informants or undercover agents is frequently if not normally essential to the successful prosecution of cases arising under the Controlled Substances Act. It was said that in the form originally proposed, the section would cut off from treatment those who might agree to cooperate with law enforcement authorities, a result both inhumane and counterproductive. As the definition of an informant is intended to make clear, however, it is his function vis-a-vis personnel and fellow patients in the program in which he is enrolled, which is controlling, and not his relationship, *per se*, with an investigative agency.

(f) Finally, the definition of informant is intended to clarify the distinction between an informant and an ordinary witness. It is the element of prearrangement which is crucial. In one of the comments received on §2.19 as proposed, it was urged that treatment programs should be considered as sanctuaries, but such a result was explicitly disclaimed in the

initial publication of the previous regulations (37 FR 24636). In so saying, we are by no means insensitive to the anxieties repeatedly expressed in both testimony and comments on this section, but we believe that the prohibition contained in § 2.19 and the procedures and criteria set forth in § 2.67 provide a measure of relief which is consistent with the structure and intent of the underlying statutes.

§ 2.20 Identification cards.—Rules.

(a) *Required use prohibited.* No program may require or request any patient to carry in his or her possession, while away from the program premises, an identification card or other form of identification which is issued by the program or which would tend to identify the bearer as a participant in it or any similar program.

(b) *Conditions of voluntary use.* Nothing in this section prohibits a program from issuing an identification card to a patient if the patient's counsellor or other authorized member of the program staff has explained to the patient that acceptance and use of the card is entirely voluntary and that neither an initial rejection nor a subsequent discontinuation of its use will in any way prejudice his or her record or standing in the program. In the case of any patient to whom an identification card or similar device was issued prior to the effective date of this section, or subsequent thereto in violation of this section, a counsellor or other authorized member of the program staff shall explain to the patient his right to turn it in without prejudice at any time.

(c) *On-premises exemption.* Nothing in this section prohibits a program from maintaining and using on its premises cards, photographs, tickets, or other devices, or using passwords or other information, to assure positive identification of patients, correct recording of attendance or medication, or for other proper purposes, as long as no pressure is brought on any patient to carry any such device when away from the program premises.

§ 2.20–1 Identification cards.—Basis and purpose.

Section 2.20 is in furtherance of one of the basic purposes of the statutes authorizing this part, namely, protection of patients from improper disclosure of their status as such. Regrettably, there appear to be areas where possession of a treatment program identification card can be prejudicial to a person under arrest or subjected to a search. In any part of the country, the accidental display or circulation of such a card by reason of its loss or theft could have adverse consequences for a variety of reasons. Since programs have other means of achieving the ends which identification cards are meant to serve, patients who do not wish to assume whatever risks may be involved in carrying such cards should not be compelled to do so.

§ 2.21 Disposition of discontinued program records.—Rules.

(a) *General rule.* When a program discontinues operations or is taken over or acquired by another program, its records to which this part applies with respect to any patient may, with the written consent of that patient, be turned over to the acquiring program or, if none, to any other program specified in the patient's consent. Except as otherwise provided in this section, any records to which this part applies, but for the transfer of which patient consent is not obtained, shall be either completely purged of patient identifying information, or destroyed. If any effort to obtain consent for transfer is made, it shall be by means which minimize the likelihood of accidental or incidental disclosure to any third party of the patient's identity as such.

(b) *Retention period.* Where records are required by law to be kept for a specified period, and such period does not expire until after the discontinuation or acquisition of the program, and patient consent for their transfer is not obtained, such records shall be sealed in envelopes or other containers marked or labelled as follows: "Records of [insert name of program] required to be maintained pursuant to [insert citation to law or regulation requiring that records be kept] until a date not later than December 31, [insert appropriate year]." The same procedure may be followed when it is determined to retain records for the period of any applicable statute of limitations.

(c) *Custodial retention.* Records marked and sealed in accordance with paragraph (b) of this section may be held by any lawful custodian, but may be disclosed by such custodian only under such circumstances and to such extent as would be permissible for the program in which they originated. As soon as practicable after the date specified on the label or legend required to be affixed pursuant to paragraph (b) of this section, the custodian shall destroy the records. In the case of any program terminated by reason of bankruptcy, the expense of compliance with this paragraph shall be an expense of administration of the bankrupt estate.

§ 2.21–1 Disposition of discontinued program records.—Basis and purpose.

While arguments can be made for requiring the destruction of records at the conclusion of their useful clinical life, there is wide disagreement on its span, and there are in addition research considerations which argue for an even longer period of retention. Except in the case of discontinued programs, it therefore seems best to leave this issue for determination by the programs concerned.

§ 2.22 Former employees and others.—Rules.

The prohibitions of this part on disclosure of patient records or information contained therein apply to all individuals who are personnel of treatment programs, researchers, auditors, evaluators, service organizations, or others having access to such records or information, and continue to apply to such individuals with respect to such records or information after the termination of their employment or other relationship or activity giving rise to such access.

§ 2.22–1 Former employees and others.—Basis and purpose.

The probition contained in § 2.22 is arguably an interpretation of the authorizing legislation which would be necessary as a matter of law even in the absence of this part; its validity as an exercise of the rulemaking power conferred by subsection (g) of the authorizing legislation seems beyond dispute.

§ 2.23 Relationship to State laws.—Rules.

The enactment of the provisions of law authorizing this part was not intended to preempt the field of law covered thereby to the exclusion of State laws not in conflict therewith. If a disclosure permitted under the provisions of this part, or under a court order issued pursuant thereto, is prohibited under State law, nothing in this part or in the provisions of law authorizing this part may be construed to authorize any violation of such State law. No State law, however, may either authorize or compel any disclosure prohibited by this part.

§ 2.23–1 Relationship to State laws.—Basis and purpose.

Section 2.23 sets forth publicly an interpretation which, in informal communications, has consistently been given to 21 U.S.C. 1175 since its original enactment, and clearly has equal applicability to 42 U.S.C. 4582.

§ 2.24 Relationship to section 303(a) of Public Health Service Act and section 502(c) of Controlled Substances Act.—Rules.

(a) *Research privilege description.* In some instances, there may be concurrent coverage of a program or activity by the provisions of this part and by a regulation or other administrative action under section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)). The latter two provisions of law, referred to hereinafter in this section as the research privilege sections, confer on the Secretary of Health, Education, and Welfare, and on the Attorney General, respectively, the power to authorize researchers to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subject of such research. The Secretary of Health, Education, and Welfare may grant this privilege with respect to any "research on mental health, including research on the use and effect of alcohol and other psychoactive drugs." The Attorney General's power is conferred as part of a section authorizing

research related to enforcement of laws under his jurisdiction concerning substances which are or may be subject to control under the Controlled Substances Act, but is not expressly limited to such research. Regardless of whether a grant of research privilege is made by the Secretary or by the Attorney General, it is expressly provided that persons who obtain it "may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify" the subjects of research for which the privilege was obtained.

(b) *Comparison with authority for this part.* Although they deal, in a sense, with the same subject matter, and may on occasion concurrently cover the same transactions, it is important to note the differences between the research privilege sections (21 U.S.C. 872(c) and 42 U.S.C. 242a(a)) and the provisions of law (21 U.S.C. 1175 and 42 U.S.C. 4582) which authorize this part. Briefly, these differences are as follows:

(1) Although they contain broad grants of express rulemaking authority, the provisions of law by which this part is authorized are self-executing in the sense that they are operative irrespective of whether the rulemaking authority is exercised. The protection afforded by the research privilege sections, on the other hand, can only come into existence as a result of affirmative administrative action.

(2) The provisions of law authorizing this part, as well as the provisions of this part itself, impose affirmative duties with respect to the records to which they apply; and the violation of such duties is subject to criminal penalties. To the extent that a privilege is thereby created, it grows out of the duties thus imposed. The research privilege sections, by contrast, impose no duties by their own terms, and if any duties are implied from their existence, they would have to be enforced on the basis of an implicit civil liability for damages or by equitable relief, as there are no criminal or administrative sanctions available.

(3) The exercise of the authority conferred by the research privilege sections is subject to administrative discretion, whereas in the case of the duties imposed under this part there is judicial discretion, within the limits and subject to procedures and criteria prescribed by statute and regulation, to grant relief in particular cases.

(c) *Grant of research privilege not affected by (b)(2)(C) order.* The issuance of an order under subsection (b)(2)(C) of either of the sections authorizing this part (21 U.S.C. 1175 and 42 U.S.C. 4582) in no way affects the continuing effectiveness of any exercise of the authority of the Secretary of Health, Education, and Welfare under 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) or the Attorney General under section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)).

§ 2.24–1 Relationship to section 303(a) of Public Health Service Act and section 502(c) of Controlled Substances Act.—Basis and purpose.

(a) In Pub. L. 93–282, the Congress expressly amended (by sections 122(a) and 303(a), 88 Stat. 131 and 137) the provisions of law which authorize this part, expressly amended (by section 122(b), 88 Stat. 132) the research privilege section under the Secretary's jurisdiction, and made explicit reference (in section 303(d), 88 Stat. 139) to the regulations previously issued by the Special Action Office for Drug Abuse Prevention reconciling the provisions of section 408 of the Drug Abuse Office and Treatment Act of 1972 with the provisions of the research privilege sections. When the bill which became Pub. L. 93–282 was before the House of Representatives for its last Congressional consideration before transmission to the President, its floor manager, Chairman Staggers of the Committee on Interstate and Foreign Commerce, inserted in the Record a detailed analysis of the bill in its final form (Congressional Record, daily edition, May 6, 1974, page H3563). This analysis contained the following paragraph:

> The relationship of section 303(a) of the Public Health Service Act, authorizing the administrative grant of absolute confidentiality for research, to section 408 of the Drug Abuse Office and Treatment Act of 1972, requiring that Federally-connected drug abuse patient records generally be kept confidential, has been correctly described in an interpretative regulation, 21 C.F.R. 1401.61 and 1401.62, which was upheld in *People v. Newman*, 32 N.Y. 2d 379, [reversing] 336 N.Y.S. 2d 127, 298 N.E. 2d 651 (1973); *certiorari* denied, [414] U.S. [1163], 94 S. Ct. 927, [39 L. Ed. 2d 116], (1974). For that reason, among others, section 303(d) of the Senate amendment expressly continues the effectiveness of the current regulation promulgated by the Director of the Special Action Office for Drug Abuse Prevention. Thus, although section 502(c) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 is not explicitly referred to in this legislation, the congressional intent is clear that the authority conferred by that section was not modified by Pub. L. 92–255, and is not intended to be modified by the bill now before the House.

(b) Sections 2.24 and 2.61 restate, in substance, the interpretative rules (§§ 1401.61 and 1401.62 of the previous regulations) referred to in the passage quoted in paragraph (a) of this section, modified to reflect the amendment made to section 303(a) of the Public Health Service Act (42 U.S.C. 242(a)) by Pub. L. 93–282.

Subpart C—Disclosures With Patient's Consent

§ 2.31 Written consent required.—Rules.

(a) *Form of consent.* Except as otherwise provided, a consent for a disclosure under this part must be in writing and must contain the following:

(1) The name of the program which is to make the disclosure.

(2) The name or title of the person or organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose or need for the disclosure.

(5) The extent or nature of information to be disclosed.

(6) A statement that the consent is subject to revocation at any time except to the extent that action has been taken in reliance thereon, and a specification of the date, event, or condition upon which it will expire without express revocation.

(7) The date on which the consent is signed.

(8) The signature of the patient and, when required under § 2.15, the signature of a person authorized to give consent under that section; or, when required under § 2.16, the signature of a person authorized to sign under that section in lieu of the patient.

(b) *Duration of consent.* Any consent given under this subpart shall have a duration no longer than that reasonably necessary to effectuate the purpose for which it is given.

(c) *Disclosure prohibited with deficient consent.* No program may disclose any information on the basis of a consent form—

(1) which on its face substantially fails to conform to any of the requirements set forth in paragraph (a), of this section, or

(2) which is known, or in the exercise of reasonable care should be known, to the responsible personnel of the program to be materially false in respect to any item required to be contained therein pursuant to paragraph (a) of this section.

(d) *Falsification prohibited.* No person may knowingly make, sign, or furnish to a program any consent form which is materially false with respect to any item required to be contained therein pursuant to paragraph (a) of this section.

§ 2.31–1 Written consent required.—Basis and purpose.

(a) The use of a consent form containing all of the elements specified in § 2.31(a) is necessary to assure compliance with the requirements of this subpart. Under § 1401.21 of the previous regulations, a much more abbreviated form was permissible, because the circumstances under which any consent could be given were very strictly limited. Now that the authorizing legislation permits disclosure with consent "to such extent, under such circumstances, and for such purposes as may be allowed under regulations," the consent form should show on its face information sufficient to indicate compliance with the regulations.

(b) Sections 2.31(b), 2.31(c), and 2.31(d) are an exercise of the general rulemaking authority in subsection (g) of the authorizing legislation. Section 2.31(c) imposes a legal liability on programs and their personnel for disclosure of information on the basis of a materially

deficient consent, and § 2.31(d) imposes liability on any person who submits a falsified consent form to a program.

§ 2.32 Prohibition on redisclosure.—Rules.

(a) *Notice to accompany disclosure.* Whenever a written disclosure is made under authority of this subpart, except a disclosure to a program or other person whose records pertaining to the patient are otherwise subject to this part, the disclosure shall be accompanied by a written statement substantially as follows: "This information has been disclosed to you from records whose confidentiality is protected by Federal law. Federal regulations (42 CFR Part 2) prohibit you from making any further disclosure of it without the specific written consent of the person to whom it pertains, or as otherwise permitted by such regulations. A general authorization for the release of medical or other information is NOT sufficient for this purpose." An oral disclosure may be accompanied or followed by such a notice.

(b) *Consent required for redisclosure.* A person who receives information from patient records and has been notified substantially in accordance with paragraph (a) of this section is prohibited from making any disclosure of such information except with the specific written consent of the person to whom it pertains, or as otherwise permitted under this part.

(c) *Restriction on redisclosure.* Whenever information from patient records is needed by any person, such information must be obtained directly from the program maintaining such records and not from another person to whom disclosure thereof has been made, except where the initial disclosure was intentionally and expressly made for the purpose of redisclosure (as for example in the case of an employment agency), or the information is no longer available from the program and redisclosure is not prohibited by any other provision of this part.

§ 2.32–1 Prohibition on redisclosure.—Basis and purpose.

(a) Section 2.32 is intended to provide a reasonable protection against redisclosure of information disclosed with consent in accordance with this subpart. There is, of course, no problem where the information becomes part of a record which is itself subject to this part because it is maintained in connection with the performance of a covered substance abuse prevention function. The difficulty arises when the disclosure is made to those whose records are not otherwise affected by this part. To attempt to make all of the provisions of this part applicable to such recipients with respect to such information might raise serious problems of legality, administrative feasibility, and fairness, but where they are given actual notice that specific patient consent is normally required for redisclosure, we think they can and should be bound by it.

(b) Oral disclosures are not mandatorily covered because they should rarely be made to any recipient with whom the program does not have a continuing relationship. Where such a relationship exists or the program is otherwise satisfied that the recipient understands and will respect the confidential nature of the information supplied, there seems no need to add to the already heavy load of paperwork with which programs must contend.

§ 2.33 Diagnosis, treatment, and rehabilitation.—Rules.

(a) *Disclosure authorized.* Where consent is given in accordance with § 2.31, disclosure of information subject to this part may be made to medical personnel or to treatment or rehabilitation programs where such disclosure is needed in order to better enable them to furnish services to the patient to whom the information pertains.

(b) *Traveling, incarcerated, or hospitalized patients on medication.* Where a patent on medication is at a distance from his normal residence or treatment program or is incarcerated or hospitalized, or is otherwise unable to deliver a written consent to his treatment program at the time the disclosure is needed, confirmation of the patient's status and information necessary to appropriately continue or modify his medication may be given to medical personnel in a position to provide services to the patient upon the oral representation of such personnel that the patient has requested medication and consented to such disclosure. Any program making a disclosure in accordance with this paragraph shall make a written memorandum showing the name of the patient, or the patient's case number assigned by the program, the date and time the disclosure was made, the information disclosed, and the names of the individuals by whom and to whom it was made.

§ 2.33–1 Diagnosis, treatment, and rehabilitation.—Basis and purpose.

(a) Section 2.33(a) is a restatement of the policy set forth in § 1401.22(a) of the previous regulations, expanded to make explicit reference to nonmedical counselling and other treatment and rehabilitative services.

(b) Section 2.33(b) clarifies the corresponding provision in § 1401.22(a) of the previous regulations by specifying how and through whom oral consent can be given, and limiting the disclosure to that necessary to determine appropriate medication.

§ 2.34 Prevention of certain multiple enrollments.—Rules.

(a) *Definitions.* For the purposes of this section and § 2.55—

(1) The terms "administer", "controlled substance", "dispense", "maintenance treatment", and "detoxification treatment" shall respectively have the meanings defined in paragraphs (2), (6), (10), (27), and (28) of section 102 of the Controlled Substances Act (21 U.S.C. 802).

(2) The term "program" means a program which offers maintenance treatment or detoxification treatment.

(3) The term "permissible central registry" means a qualified service organization which collects or accepts, from two or more programs (referred to hereinafter as member programs) all of which are located either within a given State or not more than 125 miles from the nearest point on the border of such State, patient identifying information about persons applying for maintenance treatment or detoxification treatment for the purpose of enabling the member programs to prevent any individual from being concurrently enrolled in more than one such program.

(b) *Use of central registries prohibited except as expressly authorized.* The furnishing of patient identifying information by a program to any central registry which fails to meet the definition of a permissible central registry set forth in paragraph (a)(3) of this section is prohibited, and the furnishing of patient identifying information to or by any central registry except as authorized in this section is prohibited. Information pertaining to patients held by a central registry may be furnished or used in accordance with paragraphs (e), (f), and (g) for the purpose of preventing multiple enrollments, but may not be otherwise furnished or used in connection with any legal, administrative, supervisory, or other action with respect to any patient.

(c) *Safeguards and procedures required.* To minimize the likelihood of disclosures of information to impostors or others seeking to bring about unauthorized or improper disclosure, any communications carried on by programs pursuant to this section must be conducted (1) by authorized personnel designated in accordance with § 2.17(b), and (2) in conformity with procedures established in accordance with that section.

(d) *Disclosures with respect to patients in treatment.* A member program may supply patient identifying information and information concerning the type of drug used or to be used in treatment and the dosage thereof, with relevant dates, to a permissible central registry with respect to any patient—

(1) When the patient is accepted for treatment,

(2) When the type or dosage of the drug is changed, and

(3) When the treatment is interrupted, resumed, or terminated.

(e) *Disclosures with respect to applications.* When any person applies to a program for maintenance treatment or detoxification treatment, then for the purpose of inquiring whether such person is currently enrolled in another program for such treatment, the program may furnish patient identifying information with respect to such person—

(1) To any permissible central registry of which the program is a member, and

(2) To any other program which is not more than 200 miles distant and which is not a member of any central registry of which the inquiring program is a member.

(f) *Program procedure in case of apparent concurrent enrollment.* When an inquiry pursuant to paragraph (e) (2) is made of another treatment program and its response is affirmative, the two programs may engage in such further communication as may be necessary to establish whether an error has been made, and if none, the programs should proceed in accordance with sound clinical practice and any applicable regulations pertaining to the type of treatment involved.

(g) *Registry procedure in case of apparent concurrent enrollment.* When an inquiry pursuant to paragraph (e) (1) is made of a permissible central registry and its response is affirmative, it may advise the inquiring program of the name, address, and telephone number of the other program, or it may advise the other program of the identity of the patient and the name, address, and telephone number of the inquiring program, or it may do both, and in any case the two programs may then communicate as provided in paragraph (f) above.

(h) *Advice to patients.* When the policies and procedures of any program involve any disclosures pursuant to this section, before any patient is accepted for or continued in treatment (other than detoxification treatment) after September 30, 1975, written consent in accordance with § 2.31 shall be obtained. Such consent shall set forth a current list of the names and addresses either of any programs or of any central registries to which such disclosures will be made. Notwithstanding the requirement of § 2.31 (a) (2), such consent shall be effective with respect to any other such program thereafter established within 200 miles, or any registry serving such programs, and shall so state. Such consent shall be effective for as long as the patient remains enrolled in the program to which it is given.

§ 2.34–1 Prevention of certain multiple enrollments.—Basis and purpose.

Section 2.34 is based upon § 1401.43 of the previous regulations. It was omitted from the August 22, 1974 draft, but comments on the omission made it clear that in certain areas of the country, central registries are a functional component of the treatment system, and that regulations to guide their operations are needed.

§ 2.35 Legal counsel for patient.—Rules.

When a bona fide attorney-client relationship exists between an attorney-at-law and a patient, disclosure of any information in the patient's records may be made to the attorney upon the written application of the patient endorsed by the attorney. Information so disclosed may not be further disclosed by the attorney.

§ 2.35–1 Legal counsel for patient.—Basis and purpose.

Section 2.35 simplifies and broadens the statement of the policy embodied in § 1401.25 of the previous regulations. Its purpose is to assure the availability to the attorney, with his client's consent, of any information needed as a basis for advice and counsel. The purpose of the prohibition on further disclosure by the attorney is to guard against the possibility that the attorney might be forced to serve as a conduit for otherwise prohibited disclosures to third parties. Ordinarily, the attorney-client privilege would suffice, but that privilege is subject to waiver by the client, whereas this prohibition is not. Where there is a need for disclosure to a third party of any given information about any patient, this prohibition in no way affects the availability of other sections of this part to authorize such disclosure by the program.

§ 2.36 Patient's family and others.—Rule.

Where consent is given in accordance with § 2.31, information evaluating his current or past status in a treatment program may be furnished to any person with whom the patient has a personal relationship unless, in the judgment of the person responsible for the patient's treatment, the disclosure of such information would be harmful to the patient.

§ 2.36–1 Patient's family and others.—Basis and purpose.

Section 2.36 expresses the same policy as was embodied in § 1401.27 of the previous regulations, broadened to reflect the expanded authority for consensual disclosure under the authorizing legislation.

§ 2.37 Third-party payers and funding sources.—Rules.

(a) *Acquisition of information.* Disclosure of patient information to third-party payers or funding sources may be made only with the written consent of the patient given in accordance with § 2.31 and any such disclosure must be limited to that information which is reasonably necessary for the discharge of the legal or contractual obligations of the third-party payer or funding source.

(b) *Prohibition on disclosure.* Where a funding source or third-party payer maintains records of the identity of recipients of treatment or rehabilitation services for alcohol or drug abuse such records are, under the authorizing legislation, maintained in connection with the performance of an alcohol or drug abuse prevention function and are subject to the restrictions upon disclosure set forth in this part.

§ 2.37–1 Third-party payers and funding sources.—Basis and purpose.

Section 2.37 is based upon the general authority to prescribe regulations to carry out the purposes of the authorizing legislation. The great diversity of contractual arrangements and legal requirements under which the operations of third-party payers and funding sources are carried on precludes the prescription of detailed records management instructions in these regulations, even if that were otherwise desirable. The general principles set forth in § 2.37, however, should clarify the question of coverage, and where coverage exists, provide a standard which will minimize the likelihood of violations. See also § 2.12–1(g).

§ 2.38 Employers and employment agencies.—Rules.

(a) *Disclosure permitted.* Where consent is given in accordance with § 2.31, a program may make disclosures in accordance with this section.

(b) *Eligible recipients.* A program may make disclosures under this section to public or private employment agencies, employment services, or employers.

(c) *Scope of disclosure.* Ordinarily, disclosures pursuant to this section should be limited to a verification of the patient's status in treatment or a general evaluation of progress in treatment. More specific information may be furnished where there is a bona fide need for such information to evaluate hazards which the employment may pose to the patient or others, or where such information is otherwise directly relevant to the employment situation.

(d) *Criteria for approval.* A disclosure under this section may be made if, in the judgment of the program director or his authorized representative appointed as provided in § 2.17(b), the following criteria are met:

(1) The program has reason to believe, on the basis of past experience or other credible information (which may in appropriate cases consist of a written statement by the employer), that such information will be used for the purpose of assisting in the rehabilitation of the patient and not for the purpose of identifying the individual as a patient in order to deny him employment or advancement because of his history of drug or alcohol abuse.

(2) The information sought appears to be reasonably necessary in view of the type of employment involved.

§ 2.38–1 Employers and employment agencies.—Basis and purpose.

Section 2.38 is based on the rulemaking power conferred by subsection (b) (1) of the authorizing legislation, and is adapted from § 1401.26 of the previous regulations. Its purpose is to allow disclosures reasonably necessary and appropriate to facilitate the employment of patients and former patients, while protecting patients against unnecessary or excessively broad disclosures. It was urged in a comment received on the August 22, 1974 draft that disclosures to employers be flatly prohibited on the ground that the employer's sole legitimate concern is with on-the-job performance. While we are not unsympathetic to this view, a countervailing consideration is that in the case of an employee or applicant who is known by the employer to have a problem with drugs or alcohol, knowledge by the employer of a genuine effort by the employee to deal with it can make the difference between a job and no job.

§ 2.39 Criminal justice system referrals.—Rules.

(a) *Consent authorized.* Where participation by an individual in a treatment program is made a condition of such in-

dividual's release from confinement, the disposition or status of any criminal proceedings against him or the execution or suspension of any sentence imposed upon him, such individual may consent to unrestricted communication between any program in which he is enrolled in fulfillment of such condition and (1) the court granting probation, or other post-trial or pretrial conditional release, (2) the parole board or other authority granting parole, or (3) probation or parole officers responsible for his supervision.

(b) *Duration of consent.* Where consent is given for disclosures described in paragraph (a) of this section, such consent shall expire sixty days after it is given or when there is a substantial change in such person's status, whichever is later. For the purposes of this section, a substantial change occurs in the status of a person who, at the time such consent is given, has been—

(1) Arrested, when such person is formally charged or unconditionally released from arrest;

(2) Formally charged, when the charges have been dismissed with prejudice, or the trial of such person has been commenced;

(3) Brought to a trial which has commenced, when such person has been acquitted or sentenced;

(4) Sentenced, when the sentence has been fully executed.

(c) *Revocation of consent.* An individual whose release from confinement, probation, or parole is conditioned upon his participation in a treatment program may not revoke a consent given by him in accordance with paragraph (a) of this section until there has been a formal and effective termination or revocation of such release from confinement, probation, or parole.

(d) *Restrictions on redisclosure.* Any information directly or indirectly received pursuant to this section may be used by the recipients thereof only in connection with their official duties with respect to the particular individual with respect to whom it was acquired. Such recipients may not make such information available for general investigative purposes, or otherwise use it in unrelated proceedings or make it available for unrelated purposes.

§ 2.39–1 Criminal justice system referrals.—Basis and purpose.

(a) On the basis of extensive written comment and oral communications received on the subject matter of § 2.39 as proposed in the May 9, 1975 notice (designated as § 2.40 in that notice), we have concluded that the latitude allowed and the conditions imposed in § 2.39 as set forth above are necessary and proper to effectuate the purposes of the authorizing legislation.

(b) From a legal standpoint, it seems highly doubtful whether, in a proceeding to revoke probation or parole, the due process requirements laid down in *Morrissey v. Brewer*, 408 U.S. 471, 92 S.Ct. 2593, 33 L.Ed.2d 484 (1972) and *Gagnon v. Scarpelli*, 411 U.S. 778, 93 S.Ct. 1756, 36 L.Ed.2d 656 (1973) could be met by an unsupported general evaluation by a treatment program to the effect that a patient's status or progress in treatment was unsatisfactory. Thus, if such an evaluation were all that could be communicated by a program about a particular patient's conduct during the period he was in treatment, a condition requiring satisfactory participation in a treatment program would to all intents and purposes become unenforceable. Moreover, if it were held to be enforceable, the operative decision on the revocation issue would then be made by the program, arguably exacerbating rather than alleviating its role-conflict problem. It may thus be the part of wisdom to confess that some degree of role-conflict is inherent in the situation of any program which accepts criminal justice referrals. If so, the issue then becomes that of finding the most constructive way to handle the conflict, rather than a sterile and futile effort to avoid it altogether.

(c) We are persuaded that in many instances a prohibition on free communication between probation officers and drug abuse program counsellors would have profoundly deleterious effects on the rehabilitative process. Many probation officers bring to their work a high degree of training, professionalism, and experience. They are under no illusion that they are dealing with a clientelle which will never stumble or relapse, and if they have the information necessary to intervene at an early stage of such an episode, their intervention can often make the difference between success and failure for the client.

(d) There is, however, nothing in these regulations which precludes treatment programs from entering into agreements or arrangements with agencies or institutions of the criminal justice system to regulate or restrict the subject matter or form of communications of information about patients. For example, such an arrangement might provide for free oral communication between counsellors and probation officers, while restricting formal written reports by the program to specified types of so-called hard data such as attendance and urinalysis results. In view of widely differing conditions and attitudes in various parts of the country, substantial variations in such arrangements are not only expectable but desirable.

(e) A further aspect of this matter, which was not adequately considered or dealt with in the May 9 proposal, is the impact which the rules laid down in § 2.39 have on the bail decision. There is a high correlation between the disposition of the application for bail and the type of sentence which may be meted out upon conviction. The contrast between the recidivism rates for those who receive treatment and supervision, as against those who simply receive the punishment of incarceration, is a powerful argument against restrictions which would tend to narrow the circumstances under which conscientious judges can grant bail.

(f) It must be emphasized that § 2.39 in no way reduces the necessity to obtain written consent from patients, whether or not referred by the criminal justice system, before disclosures for the purposes here involved can be made by programs. We have been urged to make an exception from the requirement of § 2.31 in the case of parolees and probationers, but such an exception would be wholly unsupported by the authorizing legislation. In fashioning these regulations, it is not our privilege to adorn a tabula rasa according to our own predilections: rather, it is our duty to interlineate a statute with fidelity to its spirit, its terms, and its purposes.

§ 2.40 Situations not otherwise provided for.—Rules.

(a) *Criteria for approval.* In any situation not otherwise specifically provided for in this subpart, where consent is given in accordance with § 2.31, a program may make a disclosure for the benefit of a patient from the records of that patient if, in the judgment of the program director or his authorized representative appointed as provided in § 2.17, all of the following criteria are met:

(1) There is no suggestion in the written consent or the circumstances surrounding it, as known to the program, that the consent was not given freely, voluntarily, and without coercion.

(2) Granting the request for disclosure will not cause substantial harm to the relationship between the patient and the program or to the program's capacity to provide services in general.

(3) Granting the request for disclosure will not be harmful to the patient.

(b) *Circumstances deemed beneficial.* For the purposes of this section, the circumstances under which disclosure may be deemed to be beneficial to a patient include, but are not limited to, those in which the disclosure may assist the patient in connection with any public or private claim, right, privilege, gratuity, grant or other interest accruing to, or for the benefit of, the patient or the patient's immediate family. Examples of the foregoing include welfare, medicare, unemployment, workmen's compensation, accident or medical insurance, public or private pension or other retirement benefits, and any claim or defense asserted or which is an issue in any civil, criminal, administrative or other proceeding in which the patient is a party or is affected.

§ 2.40–1 Situations not otherwise provided for.—Basis and purpose.

(a) Section 2.40 is based upon §1401.23 of the previous regulations, amended to reflect the expansion made by the change in the law with respect to the permissible scope of consensual disclosures.

(b) A strong case can be made for the proposition that § 2.40 should, in effect if not expressly, require a program to make any disclosure requested by a patient. The discretion vested in the program, it can be argued, is at best an expression of overprotective paternalism, and at worst, an invitation to programs to cover up material potentially embarrassing to themselves. Bearing in

mind, however, that persons who have obtained the type of treatment to which this part applies are more vulnerable to pressures of various kinds than are patients in general, it seems preferable to retain some responsibility on the part of the program to protect the best interests of its patients in this very sensitive area. This, like many other choices which these regulations reflect, is a determination which can be reviewed and revised from time to time in the light of experience.

Subpart D—Disclosures Without Patient Consent

§ 2.51 Medical emergencies.—Rules.

(a) *In general.* Disclosure to medical personnel, either private or governmental, is authorized without the consent of the patient when and to the extent necessary to meet a bona fide medical emergency.

(b) *Food and Drug Administration.* Where treatment involves the use of any drug, and appropriate officials of the Food and Drug Administration determine that the life or health of patients may be endangered by an error in the manufacture or packaging of such drug, disclosure of the identities of the recipients of the drug may be made without their consent to appropriate officials of the Food and Drug Administration to enable them to notify the patients or their physicians of the problem in order that corrective action may be taken.

(c) *Incapacitated persons.* Where a patient is incapacitated and information concerning the treatment being given him by a program is necessary to make a sound determination of appropriate emergency treatment, such information may be given without the patient's consent to personnel providing such emergency treatment.

(d) *Notification of family or others.* When any individual suffering from a serious medical condition resulting from drug or alcohol abuse is receiving treatment at a facility which is within the scope of this Part the treating physician may, in his discretion, give notification of such condition to a member of the individual's family or any other person with whom the individual is known to have a responsible personal relationship. Such notification may not be made without such individual's consent at any time such individual is capable of rational communication.

(e) *Record required.* Any program making an oral disclosure under authority of this section shall make a written memorandum showing the patient's name or case number, the date and time the disclosure was made, some indication of the nature of the emergency, the information disclosed, and the names of the individuals by whom and to whom it was disclosed.

§ 2.51–1 Medical emergencies.—Basis and purpose.

The provisions of § 2.51 are adapted from § 1401.42 of the previous regulations, and are based on subsection (b)(2)(A) of the authorizing legislation. The provision in the previous regulations with respect to patients who may be incarcerated is now covered in § 2.33(b).

Paragraph (d) of § 2.51 is based upon the theory that the disclosure there allowed is of the patient's endangered condition, not his identity as a drug or alcohol abuse patient, and that the humanitarian necessity of such notification outweights its potential for accidental violation of confidentiality.

§ 2.52 Research, audit, and evaluation.—Rules.

(a) *Research, audit, and evaluation.* Subject to any applicable specific provision set forth hereinafter in this subpart, the content of records pertaining to any patient which are maintained in connection with the performance of a function subject to this part may be disclosed, whether or not the patient gives consent, to qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner. For the purposes of this subpart and for the purposes of subsection (b)(2)(B) of the authorizing legislation, the term "qualified personnel" means persons whose training and experience are appropriate to the nature and level of the work in which they are engaged and who, when working as part of an organization, are performing such work with adequate administrative safeguards against unauthorized disclosures.

(b) *Use of disclosures of patient identifying information.*

(1) Where a disclosure made to any person pursuant to paragraph (a) of this section includes patient identifying information with respect to any patient, such information may not be further disclosed; and may not be used in connection with any legal, administrative, supervisory, or other action whatsoever with respect to such patient, except as provided in paragraphs (b)(2) and (b)(3) of this section.

(2) The inclusion of patient identifying information in any written or oral communication between a person to whom a disclosure has been made pursuant to paragraph (a) and the program making such disclosure does not constitute the identification of a patient in a report or otherwise in violation of paragraph (a).

(3) Where a disclosure is made pursuant to paragraph (a) of this section to a person qualified to determine, on the basis of such disclosure, the presence of a substantial risk to the health and well being, whether physical or psychological, of any patient, and, in the judgment of such person, such a risk exists and the situation cannot be dealt with solely by means of communications as described in paragraph (b)(2) of this section without intensifying or prolonging the risk as compared with other means of dealing with it, then the initial disclosure under paragraph (a) and any subsequent disclosure or redisclosure of patient identifying information for the purpose of reducing the risk to the patient involved shall be subject to the provisions of § 2.51.

§ 2.52–1 Research, audit, and evaluation.—Basis and purpose.

(a) *General purpose.* Subsection (a) of this section is adapted directly from subsection (b)(2)(B) of the authorizing legislation. The purpose of each is the same: To facilitate the search for truth, whether in the context of scientific investigation, administrative management, or broad issues of public policy, while at the same time safeguarding the personal privacy of the individuals who are the intended beneficiaries of the process or program under investigation. This subpart in particular, and this part as a whole, are intended to aid in carrying out that purpose.

(b) The succeeding sections of this subpart deal with problems which arise in connection with disclosures made for certain specific purposes which have been interpreted as falling within the general purposes embraced by § 2.52. Those sections will be best understood, however, in the light of some discussion of the underlying premises of the general rule, and its relationship to two other legal concepts: the right of privacy, and the duty to obtain informed consent from research subjects.

(c) *The Right of Privacy.* So far as is relevant to this discussion, we may consider the right of privacy in two aspects. One, a protection against improper governmental activity, is the right to be secure against unreasonable searches and seizures guaranteed by the Fourth Amendment, with some expansion from the penumbras of the Fifth and Sixth Amendments. The protections afforded to patients by the authorizing legislation, not to mention these regulations, go far beyond those which are constitutionally required.

(d) The other aspect of the right of privacy, which has sometimes been described as the right to be left alone, is the notion that an individual has a right not to be hurt by intrusions into his essentially personal concerns, or to have essentially private information exploited for commercial gain, whether or not the intrusion or exploitation is in connection with any possible governmental action against him. The courts have spoken of a right of privacy in a wide variety of contexts, but they have repeatedly and explicitly rejected the notion that anyone has a right to go about his daily affairs encapsulated in an impenetrable bubble of anonymity. The courts have been careful to weigh the competing interests, and the social interest in valid research and evaluation is clearly of sufficient moment to be considered in this process.

(e) In defense of the position that disclosure of patient identifying information even for carefully guarded scientific research should be permitted only on a consensual basis, two dominant lines of argument, somewhat interrelated, have emerged. One is that retrospective

studies are of questionable value in any case, and the other is that a sampling technique involving informed consent on the part of the members of the sample can always be used to develop the information sought. Neither line of argument will withstand careful scrutiny.

(f) It is true, of course, that the efficacy of a given therapeutic agent can often best be evaluated by means of a well-designed prospective study in which special recordkeeping procedures, special criteria for patient selection, and an appropriate control have all been established with a view to the purpose of the study. There are, however, many important investigations which simply do not lend themselves to such a format. Sometimes the desirability or even the possibility of a particular study does not suggest itself except in retrospect. Another important consideration is the fact that knowledge that an investigation is going on may influence the behavior of patients, clinicians, or both. Where such knowledge can influence the make-up of a sample, it will normally do so in the direction of favorable outcomes, but to an unknown degree, thus tending to invalidate the results reported.

(g) While the sample technique has its uses, especially with populations that are unmanageably large, it is often less difficult and expensive, and less likely to interfere with the actual conduct and outcomes of treatment or rehabilitation processes, to use the full population under study. Even more important than economy and administrative convenience in carrying out a study, there may be an overriding advantage in terms of eliminating any question as to the validity of the results of the study on the ground of bias in the selection of the sample.

(h) *Informed Consent.* The duty to obtain informed consent is obvious and compelling in situations where an individual is exposed to the possibility of harm, either physical or psychological, as a consequence of medical procedures, research, or similar activities. Where such a situation exists the person conducting the research or medical procedure violates his duty to the subject or patient if he proceeds without obtaining the voluntary informed consent from the individual or his legally authorized representative. Thus, in conducting an activity which places the subject or patient at risk the practitioner may not give precedence to a hidden agenda, even for so lofty a motive as the advancement of knowledge. In this regard, see the Department of Health, Education and Welfare's Protection of Human Subjects Regulations, 45 CFR Part 46. Those regulations are applicable to all Department of Health, Education and Welfare grants and contracts supporting research, development and related activities involving human subjects.

(i) It is apparent that the foregoing rationale for requiring informed consent does not apply to the same degree in situations involving the disclosure of clinical records for research in the form of follow-up or retrospective studies. Under these circumstances the risk to the subject is that some disclosure or misuse of information from which he could be identified might result in embarrassment, lost opportunities, or other forms of psychological or social injury. While that possibility of harm could be reduced by requiring consent to every review of clinical records for research purposes, a similar result can be achieved by the less restrictive method of limiting further disclosure of identifying information by the researcher. Given the applicability of this alternative, equally effective means for protecting a patient or subject from the possibility of a harmful public disclosure, it is unreasonable to insist upon informed consent to every review of clinical records for the purposes of conducting legitimate research, particularly since such insistence could lead to the ultimate absurdity of prohibiting efforts to identify the nature and source of an unknown plague simply because the patients or researcher lacked the clairvoyance to have consent forms signed prior to the onset of the affliction.

(j) In sum, there are restraints on certain means of governmental acquisition of information about individuals which are operative irrespective of how the information is used, and there are restraints on the uses of information which are independent of how or by whom it is acquired, but they do not and should not add up to the proposition that the use of information about a person is either morally or legally the absolute prerogative of that person to determine.

(k) For all of these reasons, the authorizing legislation expressly provides that patient consent is not required with respect to disclosures for research, audit, and evaluation, nor does it prohibit individual patient identification in connection with such disclosures. While it is entirely appropriate to impose safeguards and procedures in connection with these activities, it would be wholly inappropriate to use the rulemaking process to impose an absolute requirement of patient consent with respect to activities which by statute may be conducted without it.

(l) *Classification of activities.* It is clear that Congress intended a balancing of the social interest in the validity of the results of inquiry, on the one hand, with the individual interest in anonymity, on the other, all within the limits set by the legislation and the constitution. With that objective in mind, we may now turn to the various categories of activities which come within the purview of this subpart.

(m) These activities may be classified first, in regard to whether participation is voluntary from the standpoint of the program, and second, as to whether the objective is to ascertain compliance with predetermined standards (examinations as defined in § 2.54, and program evaluation as defined in § 2.11(g)(1)), or to ascertain the validity of a given standard or hypothesis (scientific research, and program evaluation as defined in § 2.11(g)(2)). The application of the foregoing classifications logically results in the creation of four categories of activities. Three of them are specifically dealt with in the succeeding sections of this subpart and need not detain us here; the fourth is discussed below.

(n) *Scientific research and evaluation.* Beyond the bare restatement of the authorizing legislation set forth in § 2.52, these regulations are deliberately silent with respect to purely voluntary scientific research and program evaluation in the sense defined in § 2.11(g)(2). Testimony and written comments received on the August 22, 1974 draft regulations were noteworthy in two respects. First, no instances of abuse on the part of persons acquiring patient identifying information under these circumstances were cited. Second, while there was some well-founded criticism of the attempt in that draft to provide guidelines for determining what is scientific research and who is qualified to do it, no usable alternatives—indeed, almost no alternatives at all—were forthcoming.

(o) In one of the written comments, the writer cautioned against any assumption "that our major remaining problems in drug and alcohol abuse treatment are prevention of illicit diversion and protection of confidentiality," and suggested "that we still have a problem in discovering, testing and evaluating improved treatment techniques. To do this," he continued, "one should place minimal obstacles in the way of bona fide clinical and epidemiologic research!"

(p) The result of leaving the rule as it is in the statute, without attempting to sharpen its outlines or define its terms, will be to leave it for interpretation on a case-by-case basis by those who must apply it in practice: the researchers who seek the information, and the programs which supply it. This does not foreclose the possibility of amending the regulations on the basis of experience if it appears either that clinicians are becoming so cautious that research and evaluation studies are being choked off, or that abuses are occurring in the use of information disclosed. But until a need for more detailed regulation in this area is demonstrated, we think its imposition would do more harm than good.

§ 2.53 Governmental agencies.—Rules.

(a) *In general.* Where research, audit, or evaluation functions are performed by or on behalf of a State or Federal governmental agency, the minimum qualifications of personnel performing such functions may be determined by such agency, subject to the provisions of this part, with particular reference to the organizational requirements and limitations on the categories of records subject to review by different categories of personnel.

(b) *Financial and administrative records.* Where program records are reviewed by personnel who lack either the responsibility for, or appropriate training and supervision for, conducting scientific research, determining adherence to treatment standards, or evaluating treatment as such, such review should be confined as far as practicable to adminis-

trative and financial records. Under no circumstances should such personnel be shown caseworker or counsellor notes, or similar clinical records. Programs should organize their records so that financial and administrative matters can be reviewed without disclosing clinical information and without disclosing patient identifying information except where necessary for audit verification.

(c) *Scientific research and long-term evaluation studies.* No State and no agency or political subdivision of a State may require, as a condition to funding, licensing, or otherwise, that any program furnish patient identifying information for the purpose of conducting scientific research or long-term evaluation studies unless the recipient of such information is legally required to hold such information in confidence, is prohibited from taking any administrative, investigative, or other action with respect to any individual patient on the basis of such information, and is prohibited from identifying, directly or indirectly, any individual patient in any report of such research or evaluation, or otherwise disclosing patient identities in any manner.

(d) *Opinion and description to be furnished program.* Before any patient identifying information is required to be submitted by a program under the circumstances described in paragraph (c), the program shall be furnished—

(1) An opinion by the attorney general or other chief legal officer of the State to the effect that the conditions specified in paragraph (c) are fulfilled with respect to such program or with respect to all programs in such State similarly situated, and

(2) A description of the administrative procedures and physical limitations on access or other measures to provide for the security of the data, but such description shall not be in such detail as to furnish guidance for wrongful attempts to breach such security.

(e) *Exclusiveness of procedures.* No State or local governmental agency may require any treatment program to furnish patient identifying information to itself or any other recipient except in conformity with this section or § 2.54. No Federal agency may require any treatment program to furnish patient identifying information to itself or any other recipient except in conformity with this section (other than paragraph (d)(1) thereof) or § 2.54.

§ 2.53–1 Governmental agencies.—Basis and purpose.

Section 2.53 is an implementation of the authority contained in subsection (g) of the authorizing legislation to provide safeguards and procedures to effectuate the purposes of such legislation. It makes clear that whenever information is required of a program, whether by law or by the terms or conditions of a contract or grant, the procedures and safeguards required under this section are applicable.

§ 2.54 Patient identifying information in connection with examinations.—Rules.

(a) *Definitions.* For the purposes of this section—

(1) The term "examination" means any examination to which this section is made applicable by paragraph (b) of this section.

(2) The term "examiner" means any individual or any public or private organization, including any Federal, State, or local governmental agency, which conducts an examination to which this section applies.

(b) *Applicability.* This section applies to any examination of the records of a treatment program which is carried out for the purpose of or as aid to ascertaining the accuracy or adequacy of its financial or other records, or the efficiency or effectiveness of its financial, administrative, or medical management, or its adherence to financial, legal, medical, administrative, or other standards, regardless of whether such examination is called an audit, an evaluation, an inspection, or by any other name.

(c) *Statement required for disclosure of patient identifying information in connection with examination.* No program may make, and no examiner may require, any disclosure of patient identifying information in connection with an examination unless the examiner furnishes to the program a written statement—

(1) that no record of patient identifying information will be made or retained by or on behalf of the examiner in connection with the examination without notice to the program in accordance with paragraph (c)(2) of this section, or

(2) setting forth the specific purpose for which a record of patient identifying information is being retained by or on behalf of the examiner, the location at which such information will be kept, and the name, official title, address, and telephone number of a responsible individual to whom any inquiries by the program about the disposition of such record should be directed.

(d) *Disposition of record of patient identifying information in connection with examination.* After any record of patient identifying information retained in connection with an examination has served its purpose, or within the time prescribed in paragraph (e) of this section, whichever is earlier, the examiner shall destroy or return to the program all records (including any copies thereof) containing patient indentifying information which have been in its possession in connection with such examination.

(e) *Maximum time allowed for disposition.* The action required by paragraph (d) shall be completed—

(1) Except as provided in paragraph (e)(2) of this section not more than two years after the record was acquired by or on behalf of the examiner, or

(2) Where the record is needed in connection with a formal legal proceeding against the program commenced or to be commenced not more than two years after the record was acquired, and written notice to this effect is furnished to the program within two years after the record was acquired, not later than the termination of such proceeding.

(f) *Notice of final disposition.* When an examiner disposes of records as required by paragraph (d) of this section, or not later than the time prescribed by paragraph (e) of this section, whichever is earlier, the examiner shall furnish to the program concerned a written statement—

(1) That there has been compliance with this section and with the provisions of this part prohibiting any disclosure of patient identifying information from records held by auditors or evaluators, or

(2) Specifying the particulars in which there has been a failure of compliance.

§ 2.54–1 Patient identifying information in connection with examinations.—Basis and purpose.

Confidence on the part of treatment program personnel in the integrity of auditing and regulatory processes is important to the effective functioning of the treatment system. It is the purpose of § 2.54 to foster practices which will both justify and engender such confidence.

§ 2.55 Supervision and regulation of narcotic maintenance and detoxification programs.—Rules.

(a) *Definition of "registrant".* For the purposes of this section, the term "registrant" means a person who (1) has pending an application for registration under section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)), or (2) has been registered under such section and whose registration has not expired or been surrendered or revoked.

(b) *Drug Enforcement Administration.* Duly authorized agents of the Drug Enforcement Administration shall have access to the premises of registrants for the purpose of ascertaining compliance (or ability to comply) with standards established by the Attorney General under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) respecting the security of stocks of narcotic drugs and the maintenance of records (in accordance with section 307 of the Controlled Substances Act, 21 U.S.C. 827) on such drugs. Registrants shall maintain such records separate from and in addition to patients' clinical records required to be maintained under 21 CFR 310.505(d)(7)(iii), which shall not be available to such agents except as authorized under a court order in accordance with Subpart E of this part. Records maintained by registrants for the purposes of section 307 of the Controlled Substances Act (21 U.S.C. 827) need not identify patients by name, address, social security number, or otherwise except by an identifying number assigned by the registrant, but where such a system is used, the registrant shall maintain on a current basis a cross-index referencing each identifying number to the name and address of the patient to whom it refers. Upon request at any time and wtihout advance notice, but subject to the pro-

visions of § 2.54, such agents shall be granted immediate access to any such index. Such agents may use names and addresses so obtained strictly for the purposes of auditing or verifying program records, and shall exercise all reasonable precautions to avoid inadvertent disclosure of patient identities to third parties. Names and other identifying information so obtained may not be compiled or used in any registry or personal data bank of any description.

(c) *Food and Drug Administration.* Duly authorized agents of the Food and Drug Administration shall have access to the premises of registrants and to all records maintained by registrants, for the purpose of ascertaining compliance (or ability to comply) with standards established by the Secretary of Health, Education and Welfare under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (42 U.S.C. 257a), sections 303(g)(1) and 303(g)(3) of the Controlled Substances Act (21 U.S.C. 823(g)(1) and 823(g)(3)), and sections 505 and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 and 371(a)). When necessary in the conduct of their duties, and subject to the provisions of § 2.54, agents may use names and addresses of patients strictly for the purposes of auditing or verifying program records, and shall exercise all reasonable precautions to avoid inadvertent disclosure of patient identities to third parties. Names and other identifying information on patients obtained pursuant to this section or by any other compulsory process may not be compiled or used in any registry or personal data bank of any description. Except as authorized under this paragraph or by a court order granted under Subpart E of this part, (1) such agents may not, either orally or in writing, except in conversation with personnel of the registrant while on the premises of the registrant, identify any patient otherwise than by reference to an identifying number assigned by the registrant, and (2) such agents may not remove from the premises of the registrant any notes, documents, or copies thereof which contain patient identifying information.

(d) *State drug law enforcement agencies.* Duly authorized agents of any State drug law enforcement agency having jurisdiction and specific responsibility by statute or otherwise for the enforcement of criminal laws relating to controlled substances (as defined in the Controlled Substances Act) shall have access to the premises of any registrant for the purposes (with respect to corresponding provisions, if any, of State law) and subject to the restrictions and limitations set forth in paragraph (b) of this section, and subject to § 2.54.

(e) *State health authorities.*

(1) *Definition of "qualified State health agency".* As used in this paragraph, the term "qualified State health agency" means an agency of State government (i) which has express legal responsibility to ascertain that registrants under its jurisdiction comply with appropriate treatment standards; (ii) which is legally and administratively separate from any agency of State government responsible for investigation of violations of, or enforcement of, criminal law generally or criminal laws relating to controlled substances; (iii) whose personnel are qualified by training or experience to conduct inspections of health care facilities to ascertain compliance with treatment standards; and (iv) whose personnel are by State law, or by published administrative directive enforced by effective sanctions, required to maintain the confidentiality of any information concerning the identity of patients which they may acquire in the course of their official duties.

(2) *Access.* Duly authorized agents of a qualified State health agency shall have access to the premises of registrants and to all records maintained by registrants, for the purpose of ascertaining compliance (or ability to comply) with treatment standards (including those relating to quantities of narcotic drugs which may be provided for unsupervised use by individuals in treatment) established under State law. Such access, and the use of any information thereby obtained, shall be subject to the restrictions and limitations set forth in paragraph (c) of this section, and subject to § 2.54.

§ 2.55–1 Supervision and regulation of narcotic maintenance and detoxification programs.—Basis and purpose.

(a) Section 2.55 is addressed to the general problem described in the following passage from the legislative history of Pub. L. 93–282:

> A major element of the task of fashioning new regulations pursuant to the express rulemaking authority conferred by this legislation will be to reconcile the sometimes conflicting interests of research, audit, and evaluation with rights of privacy and the confidentiality of the relationship between patient and clinician. Such a reconciliation becomes particularly crucial where the functions of research, audit, or evaluation are conducted by a governmental agency with regulatory powers and responsibility, and the treatment involves the use of a drug such as methadone which is in a research status or which is readily susceptible of misuse or illicit diversion.
>
> Because of the difficulty and complexity of the task, the rulemaking authority is intentionally cast in terms broad enough to permit the limitation of the scope, content, or circumstances of any disclosure under subsection (b), whether (b)(1) or (b)(2), in the light of the necessary purposes for which it is made or required. (Congressional Record, daily edition, May 6, 1974, page H3563).

(b) It has been the consistent interpretation of the Special Action Office for Drug Abuse Prevention that the only provision of the authorizing legislation which permits disclosures to compliance officers, whether of DEA, FDA, or state agencies, is subsection (b)(2)(B). That subsection strictly prohibits any further disclosure of names or other identifying information concerning patients, and the statutory prohibition has been buttressed by provisions of these regulations, notably § 2.54, providing safeguards and procedures to assure that the statutory prohibition is respected.

(c) In testimony and written comment on the August 22, 1974 draft of these regulations, it has been urged that access to patient identifying information by law enforcement personnel, even for the limited purposes allowed by statute and regulation, should be prohibited except pursuant to a court order obtained under 21 U.S.C. 1175(b)(2)(C). We believe that such a prohibition is beyond our power to impose.

(d) Section 307(b) of the Controlled Substances Act (21 U.S.C. 827) provides, in pertinent part, "Every * * * record required under this section * * * shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General." It is a well known principle of statutory construction that amendments and repeals by implication are not favored. In *People v. Newman*, 32 N.Y.2d 379, 345 N.Y.S.2d 502, 298 N.E.2d 651 (1973), cert. denied 414 U.S. 1163, 94 S.Ct. 927, 39L. Ed. 2d 116 (1974), the United States filed *amicus* briefs with the Court of Appeals of New York and with the United States Supreme Court, arguing that section 408 of Pub. L. 92–255 (21 U.S.C. 1175) did not effect an implied amendment or repeal of the provisions of Pub. L. 91–513 (21 U.S.C. 872(c) and 42 U.S.C. 242a(a)) which confer on the Attorney General and the Secretary of Health, Education, and Welfare the power to grant the so-called research privilege discussed in § 2.24. This position was expressly adopted by the New York court. We cannot now take the inconsistent position that section 408 of Pub. L. 92–255 did indeed amend by implication section 307 of Pub. L. 91–513, particularly in the face of a contrary contemporaneous administrative interpretation by both the Special Action Office for Drug Abuse Prevention and the Department of Justice. In short, if the right of access and copying conferred on Federal agents by 21 U.S.C. 827 is to be amended to provide that it may only be exercised pursuant to a court order in the case of maintenance and detoxification programs, that is a change which must be wrought by the Congress.

(e) In the case of inspections carried out by health supervisory agencies, we think that denial of access to any documents showing patient identifying information may have a serious adverse effect on the validity of the inspection process. Even if a program keeps its own records in terms of patient-identifying numbers assigned by the program, the patient file may contain—may, indeed, be required to contain—documents signed by the patient or originating outside the program. Where signatures, names, and addresses are all obliterated, it is impossible for the inspector to check the file even for apparent internal consistency. We believe that outright forgery is and will remain a rarity, but the temptation to cover improper or inadequate documentation by "accidental misfilings" may be something else again.

(f) From a legal standpoint, the term "audit" has long comprehended the notion of external verification. In a commercial setting, this means that at least some inventory will actually be counted, at least some receivables will be verified by contacting the customers, and so on. To rule that this crucial aspect of the audit process cannot be carried out with respect to a treatment program until after the auditor goes through the procedure of obtaining a specific court order under subsection (b)(2)(C) would seem to contravene the intent of subsection (b)(2)(B).

(g) In all of this, our decisions must be illuminated by a balanced consideration of the best interests of the patient no less than a desire to foster the implementation of cherished values in society at large. If protection of the patient's right to privacy is achieved by means which seriously impair our ability to protect him from exploitation and malpractice, not to mention the diversion of funds intended for his benefit, it would be a hollow victory indeed. We believe that the procedures and safeguards which these regulations impose on the conduct of audits and evaluations will avoid that result, while affording substantial and meaningful new protection to the confidentiality of patient records.

§ 2.56 Prohibition on disclosure of patient identities from research, audit, or evaluation records—Rules.

Where the content of patient records has been disclosed pursuant to this subpart for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof either voluntarily or in response to any legal process whether Federal or State. This prohibition does not affect the accessibility of the original records under authority of a court order referred to in subpart E.

§ 2.56–1 Prohibition on disclosure of patient identities from research, audit, or evaluation records—Basis and purpose.

Section 2.56 restates the prohibition on further disclosure which is contained in subsection (b)(2)(B) of the authorizing legislation. The relationship of the provisions authorizing court orders to the provisions authorizing disclosure for research, audit, and evaluation, is dealt with in § 2.62.

Subpart E—Court Orders

§ 2.61 Legal effect of order—Rules.

Subsection (b)(2)(C) of the sections which authorize this part (21 U.S.C. 1175 and 42 U.S.C. 4582) empowers the courts, in appropriate circumstances, to authorize disclosures which would otherwise be prohibited by subsection (a) of those sections. Subsection (b)(2)(C) operates only as a mechanism for the relief of the duty imposed by subsection (a) and not as an affirmative grant of jurisdiction to authorize or compel disclosures prohibited or privileged by other provisions of law, whether Federal or State. An order or provision of an order based on some other authority, or a subpoena, or other appropriate legal process, is required to compel disclosure. To illustrate, if a person who maintains records subject to this part is merely requested, or is even served with a subpoena, to disclose information contained therein in a manner prohibited in the absence of a court order, he must refuse such a request unless, and until, an order is issued under subsection (b)(2)(C). Such an order would remove the prohibition, but could not, of its own force, require disclosure. If there were no subpoena or other compulsory process, or a subpoena had been issued but had expired or been quashed, the custodian of the records would have discretion as to whether to disclose the information sought unless and until disclosure were ordered by means of appropriate legal or administrative process, the authority for which would have to be found in some source other than subsection (b)(2)(C) of the sections authorizing this part.

§ 2.61–1 Legal effect of order—Basis and purpose.

(a) Section 2.61 is a restatement of the interpretative rules embodied in §§ 1401.61 and 1401.62 of the previous regulations. Both the positioning of the authority to issue court orders in S. 2097 as initially passed by the Senate (92nd Congress, 1st Session, December 2, 1971) and the explicit cross-reference in section 408(a) of Pub. L. 92–255 make clear the congressional intent that section 408(b)(2)(C) operate as a mechanism for the relief of the 408(a), strictures and not as an affirmative grant of jurisdiction to authorize disclosures prohibited by other provisions of law, whether Federal or State.

(b) The amendment made by Pub. L. 93–282 to section 333 of the Alcoholism-Act (42 U.S.C. 4582) was enacted with the same language and structure as section 408 in this regard in order to make the interpretative rules set forth in § 2.61 applicable to it.

§ 2.62 Inapplicability to secondary records—Rules.

The authority which subsection (b)(2)(C) of the sections which authorize this part (21 U.S.C. 1175 and 42 U.S.C. 4582) confers on courts to issue orders authorizing the disclosure of records applies only to records referred to in subsection (a) of such sections, that is, the records maintained by treatment or research programs which have patients, and not to secondary records generated by the disclosure of the subsection (a) records to researchers, auditors, or evaluators pursuant to subsection (b)(2)(B).

§ 2.62–1 Inapplicability to secondary records—Basis and purpose.

(a) The interpretative rule set forth in § 2.62 is an essential and basic limitation on the scope of (b)(2)(C) orders. It was part of the original regulations under section 408 of Pub. L. 92–255 published November 17, 1972 (37 FR 24638), and was carried forward unchanged in the amended regulations published December 6, 1973 (38 FR 33748), the special status of which has already been noted in § 2.3. See, also, § 2.61–1.

(b) Although this rule is well supported by the history and technical structure of the legislation, the policy considerations in its favor are even more compelling. In § 2.52–1, we have discussed the urgent necessity for access, even without patient consent, to patient records on the part of qualified personnel engaged in scientific research and evaluation. Where this access includes patient identifying information, as it sometimes must if vital work is to be done, there must not be any question whatsoever about the legal inviolability of its confidential status in the hands of the researcher. Granted, there may occur rare occasions when the original records are for some reason not available, where a (b)(2)(C) order would lie as to the original records, and where there would seem to be some advantage in the administration of justice for such an order to permit disclosure of identifying information by the researcher. But compared to the damage which the mere potentiality for access does to the whole research enterprise, the advantage in terms of ability to deal with rare and anomalous cases seems almost trivial. Even in those cases, denial of access to the party seeking the information leaves him in no worse position than if the research or evaluation, which was certainly not undertaken for his benefit, had never been done at all.

(c) Where the secondary records are generated under the circumstances described in § 2.54, of course, this argument does not apply. In that situation, if preliminary examination suggests that the records may be needed for compliance or other administrative or judicial proceedings, the person conducting the audit or other examination should promptly seek the authority of a court order to copy the original records. The use of secondary records thus generated under authority of a court order would then be limited by the terms and purposes of the order, rather than subsection (b)(2)(B) of the authorizing legislation, and thus the rule set forth in § 2.62 would not apply.

§ 2.63 Limitation to objective data—Rules.

(a) *Limitation to objective data.* Except as provided in paragraph (b) of this section, the scope of an order issued pursuant to this subpart may not extend to communications by a patient to personnel of the program, but shall be limited to the facts or dates of enrollment, discharge, attendance, medication, and similar objective data, and may include only such objective data as is necessary to fulfill the purposes for which the order is issued.

(b) *Exception.* When a patient in litigation offers testimony or other evidence pertaining to the content of his communications with a program, an order under this subpart may authorize

the submission of testimony or other evidence by the program or its personnel.

§ 2.63–1 Limitation to objective data.—Basis and purpose.

In the three-year period subsequent to the original enactment of 21 U.S.C. 1175, not a single occasion was reported to the Special Action Office for Drug Abuse Prevention on which an attempt was made to secure a (b)(2)(C) order authorizing the disclosure of a confidential communication by a patient to a counsellor or other member of the staff of a treatment program. In all of the comments and testimony received on the draft regulations published August 22, 1974, there was nothing to suggest any circumstances under which a court order authorizing such a disclosure would be either desirable or appropriate. Yet the mere possibility that such an order might be issued is to some a source of anxiety which impairs the effectiveness of treatment. Such an ongoing negative effect clearly outweighs the remote theoretical possibility that some peculiar circumstance might arise in which judicial authorization for such a disclosure might be sought. Accordingly, the limitation imposed by § 2.63 on the scope of (b)(2)(C) orders to preclude that possibility, and hence to eliminate its adverse influence on treatment services, appears to be a proper exercise of rulemaking power.

§ 2.64 Procedures and criteria in general—Rules.

(a) *Identity of patient.* Applications for court orders to authorize disclosure of records pertaining to a known patient shall not use the real name of the patient unless the patient consents thereto voluntarily and intelligently. In the case of an *ex parte* application initiated by the patient, the application should be instituted in the name of a fictious person, such as Jon Doe, unless the patient requests otherwise. The same procedure should be followed in the case of a separate proceeding held in conjunction with a pending criminal or civil action. Any court order should identify the patient fictitiously, and the disclosure of the patient's real name should be communicated to the program in such manner as to protect the confidentiality of the patient's identity.

(b) *Notice.* In any proceeding not otherwise provided for in this subpart, in which the patient or the program has not been made a party, each shall be given appropriate notice and an opportunity to appear in person or to file a responsive statement, deposition or other form of response consistent with local rules of procedure. The court shall give due consideration to any such statement, deposition or other response in exercising its discretion as to the existence of good cause and, if deemed necessary or desirable, consistent with local rules of procedure, it may order the program director to appear and give direct testimony.

(c) *Hearings.* All hearings and all evidence in connection therewith shall be held or taken in the judge's chambers, unless the patient requests an open hearing or the court determines that such hearing is consistent with the public interest and the proper administration of justice.

(d) *Good cause.* No order shall be issued unless the record shows that good cause exists, and in assessing good cause, the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services.

(e) *Need for disclosure.* If other competent evidence or sources of information are available, the court should ordinarily deny the application.

(f) *Adverse effects.* If there is evidence that disclosure would have an adverse effect upon successful treatment or rehabilitation of the patient or would impair the effectiveness of the program, or other programs similarly situated, in the treatment or rehabilitation of other patients, the application should be denied unless the court finds that the adverse effects are outweighed by other factors.

(g) *Content of order.* Any order authorizing disclosure shall—

(1) Limit disclosure to those parts of the patient's record deemed essential to fulfill the objective for which the order was granted;

(2) Limit disclosure to those persons whose need for information is the basis for the order; and

(3) Include any other appropriate measures to keep disclosure to a minimum for the protection of the patient, the physician-patient relationship and the treatment services.

(h) *Applications not otherwise provided for.* In any case not otherwise provided for in this subpart, application for an order authorizing disclosure of records to which this part applies may be made by any person who has a legally cognizable interest in obtaining such disclosure.

§ 2.64–1 Procedures and criteria in general.—Basis and purpose.

Section 2.64, in accordance with subsection (g) of the authorizing legislation, sets out procedures and criteria for the issuance of (b)(2)(C) orders in general, subject to the more specific provisions with respect to particular types of proceedings covered in the succeeding sections of this subpart.

§ 2.65 Investigation and prosecution of patients.—Rules.

(a) *Applicability.* This section applies to any application by an investigative, law enforcement, or prosecutorial agency for an order to permit disclosure of patient records for the purpose of conducting an investigation or prosecution of an individual who is, or who is believed to be, a present or former patient in a program.

(b) *Notice.* Except where an order under § 2.66 is sought in conjunction with an order under this section, any program with respect to whose records an order is sought under this section shall be notified of the application and afforded an opportunity to appear and be heard thereon.

(c) *Criteria.* A court may authorize disclosure of records pertaining to a patient for the purpose of conducting an investigation of or a prosecution for a crime of which the patient is suspected only if the court finds that all of the following criteria are met:

(1) The crime was extremely serious, such as one involving kidnapping, homicide, assault with a deadly weapon, armed robbery, rape, or other acts causing or directly threatening loss of life or serious bodily injury, or was believed to have been committed on the premises of the program or against personnel of the program.

(2) There is a reasonable likelihood that the records in question will disclose material information or evidence of substantial value in connection with the investigation or prosecution.

(3) There is no other practicable way of obtaining the information or evidence.

(4) The actual or potential injury to the physician-patient relationship in the program affected and in other programs similarly situated, and the actual or potential harm to the ability of such programs to attract and retain patients, is outweighed by the public interest in authorizing the disclosure sought.

(d) *Scope.* Both disclosure and dissemination of any information from the records in question shall be limited under the terms of the order to assure that no information will be unnecessarily disclosed and that dissemination will be no wider than necessary. Under no circumstances may an order under this section authorize a program to turn over patient records in general, pursuant to a subpoena or otherwise, to a grand jury or a law enforcement, investigative, or prosecutorial agency.

(e) *Counsel.* Any application to which this section applies shall be denied unless the court makes an explicit finding to the effect that the program has been afforded the opportunity to be represented by counsel independent of counsel for the applicant, and in the case of any program operated by any department or agency of Federal, State, or local Government, is in fact so represented.

§ 2.65–1 Investigation and prosecution of patients—Basis and purpose.

(a) The need for objective criteria for the issuance of court orders in connection with investigation or prosecution of patients seems particularly pressing. In the absence of such criteria, the assurance of confidentiality otherwise provided for by the authorizing legislation may be felt to be of little value.

(b) It has not been found possible to frame entirely satisfactory rules for the scope of orders under § 2.65, but an illustration may be helpful. Where a witness to a crime is believed capable of identifying a suspect by appearance, and the criteria set forth in § 2.65(c) are met, and the program has photographs of its patients, the witness alone may be permitted to view the photographs, with no names attached. If the witness failed to identify any photograph as being a pic-

ture of the suspect, that would end the matter. If there was such an identification, the program would be authorized to give any information in its possession as to the suspect's identity and whereabouts to appropriate authorities.

(c) It is not the purpose of this section to substitute a mechanical formula for judicial discretion, but rather to provide criteria which define the area within which discretion is to be exercised. The reason for including all crimes committed on program premises or against program personnel is not any special solicitude for programs as opposed to other victims of crime, but is rather the result of the special difficulties which the broad definition of "records" in § 2.11(o) creates for program personnel as complaining witnesses.

(d) In regard to § 2.65(e), experience has demonstrated that independent counsel may be of crucial importance. The leading case construing 21 U.S.C. 1175, *People v. Newman*, 32 N.Y.2d 379, 345 N.Y.S.2d 502, 298 N.E.2d 651 (1973); certiorari denied, 414 U.S. 1163, 94 S.Ct. 927, 39 L. Ed.2d 116 (1974), would never have been presented to the courts but for the fact that legal counsel for Dr. Newman was furnished on a *pro bono publico* basis by a private law firm. In an entirely different case, a United States District Court appears to have issued a wholly inappropriate order under 21 U.S.C. 1175 in a case in which the treatment program involved was operated by an agency of the United States Government, and either was unrepresented, or was represented by the same attorney who represented the agency seeking the order. It is possible, of course, that the order would have been issued in any event, but it seems clear that there was no adequate presentation to the court of arguments or testimony in opposition. It is difficult to see how the purposes of subsection (b)(2)(C) of the authorizing legislation can be carried out if there is inadequate presentation of the issues to the courts which must decide them.

§ 2.66 Investigation and prosecution of programs.—Rules.

(a) *Applicability.* This section applies to any application by an administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency for an order to permit disclosure of patient records or the making of copies thereof (including patient identifying information) for the purpose of conducting an investigation or an administrative or judicial proceeding with respect to any program or any principal, agent, or employee thereof in his capacity as such.

(b) *Notice.* An application under this section may, in the discretion of the court, be granted without notice, but upon the implementation of any order so granted, the program shall be afforded an opportunity to seek the revocation or amendment of such order.

(c) *Scope.* Both disclosure and dissemination of any information from the records in question shall be limited under the terms of the order to assure that patient identities will be protected to the maximum practicable extent, and that names and other identifying characteristics of patients are expunged from any documents placed in any public record. No information obtained pursuant to an order under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under § 2.65.

§ 2.66–1 Investigation and prosecution of programs—Basis and purpose.

The principal purpose of § 2.66 is to enable a regulatory agency whose inspection or other source of information has disclosed a need for follow-up, or which has been refused access to patient records, to obtain the necessary authorization for access and copying. There may also be rare instances, such as those involving financial fraud, tax evasion, or other offenses where access by other investigative agencies is necessary, subject to the requirements and protections of this part.

§ 2.67 Undercover agents and informants—Rules.

(a) *Applicability.* This section applies to any application by an administrative, regulatory, supervisory, investigative, or law enforcement agency for an order to permit such agency to have an undercover agent or informant in a program under circumstances which would otherwise be prohibited under § 2.19.

(b) *Notice.* An order under this section may be granted without notice where the criminal conduct for the investigation of which it is granted is believed to be carried on by the program director or by any employee or agent of the program with the knowledge of the program director or under such circumstances that in the exercise of reasonable care the program director should know of such conduct. Under any other circumstances, an order under this section may be granted only after the program director has been afforded notice and opportunity for hearing.

(c) *Criteria.* An order under this section may be granted only where there is reason to believe that a program or any principal, agent, or employee thereof is engaged in serious criminal misconduct, and that other means of securing evidence of such criminal misconduct are not available or would not be effective.

(d) *Scope.* An order granted pursuant to this section may authorize the use by the applicant of an undercover agent or informant, either as a patient or as an employee, of the program in question.

(e) *Time periods.* An order under this section may not authorize the use of an undercover agent for an initial period exceeding 60 days. At any time prior to the expiration of such 60-day period, the applicant may apply for an order extending such period for an additional period not to exceed 60 days, but in no event may the use of an undercover agent in any program be authorized for more than 180 days in any period of 12 consecutive months.

(f) *Duty of agent.* Except to the extent expressly authorized in an order under this section, which shall be limited to disclosure of information directly related to the purpose for which the order is granted, an undercover agent or informant shall for the purposes of this part be deemed an agent of the program within which he is acting as such, and as such shall be subject to all of the prohibitions of this part applicable to disclosures of any information which he may acquire.

§ 2.67–1 Undercover agents and informants—Basis and purpose.

The legal rationale underlying this section has been set forth in § 2.19–1. It is expected that this section will find its principal and perhaps its exclusive application in the area of drug law enforcement. Experience has demonstrated that medical personnel, no matter how credentialed, can engage in the illicit sale of drugs on a large scale, and that the use of undecover agents and informants is normally the only effective means of securing evidence sufficient to support a successful prosecution.

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Title 21—Food and Drugs

CHAPTER III—SPECIAL ACTION OFFICE FOR DRUG ABUSE PREVENTION

PART 1401—CONFIDENTIALITY OF DRUG ABUSE PATIENT RECORDS

Revocation of Part

On May 9, 1975, there was published in the FEDERAL REGISTER (40 FR 20542) a notice of proposed rulemaking proposing the revocation of Part 1401 of Title 21 of the Code of Federal Regulations by reason of the proposed incorporation of its subject matter in a new Part 2 of Title 42 of the Code of Federal Regulations.

Interested persons were invited to submit written comments, views, or arguments with respect to the proposed revocation, within 30 days of the date of publication of that notice. None were received, except to the extent that they were implicit in those submitted on the proposed new Part 2 of Title 42 of the Code of Federal Regulations, which were duly considered.

Accordingly, pursuant to the authority of section 408 of the Drug Abuse Office and Treatment Act of 1972, as amended by Pub. L. 93-282 (21 U.S.C. 1175), and under the authority delegated to the General Counsel (39 FR 17901, May 21, 1974), Part 1401 of Title 21 of the Code of Federal Regulations is revoked, effective August 1, 1975.

Dated: June 25, 1975.

GRASTY CREWS, II,
General Counsel, Special Action Office for Drug Abuse Prevention.

[FR Doc.75-17170 Filed 6-27-75;9:38 am]

CHAPTER 397

REHABILITATION OF DRUG DEPENDENTS

397.011 Purpose and intent of chapter; disposition of convicted offenders.—

(1) It is the purpose of this chapter to encourage the fullest possible exploration of ways by which the true facts concerning drug abuse and dependence may be made known generally and to provide a comprehensive program of human renewal for drug dependents in rehabilitation centers and aftercare programs. This program is designed to assist in the rehabilitation of persons dependent on the drugs controlled by chapters 398 and 404. It is further designed to protect society against the social contagion of drug abuse and to meet the need of drug dependents for medical, psychological, and vocational rehabilitation, while at the same time safeguarding their individual liberties.

(2) It is the intent of the Legislature to provide an alternative to criminal imprisonment for individuals capable of rehabilitation as useful citizens through techniques not generally available in state or local prison systems. For a violation of any provision of chapter 398, Uniform Narcotic Drug Law, or chapter 404, Florida Drug Abuse Law, relating to possession of any substance regulated thereby, the trial judge may, in his discretion, require the defendant to participate in a drug rehabilitation program approved or regulated by the Department of Health and Rehabilitative Services pursuant to the provisions of this chapter, provided the director of such program approves the placement of the defendant in such program. Such required participation may be imposed in addition to or in lieu of any penalty or probation otherwise prescribed by law, provided the total time of such penalty, probation, and program participation shall not exceed the maximum length of sentence possible for the offense.

History.—s. 1, ch. 70-183; s. 3A, ch. 71-222.

397.021 **Definitions.**—When used in this chapter, unless the context otherwise requires:

(1) "Department" means the Department of Health and Rehabilitative Services.

(2) "Drug dependent" means a person who is dependent upon, or by reason of repeated use is in imminent danger of becoming dependent upon, any substance controlled under chapter 893.

(3)(a) "DATE center" means a drug abuse treatment and education center, and includes, but is not limited to, the following:

1. A residential rehabilitation center, which is a live-in facility operating 24 hours a day, 7 days a week, staffed by professional and para-professional persons offering therapeutic programs for drug dependent persons.

2. A nonresidential day-care center, which is a facility offering therapeutic programs operated by trained professional and para-professional persons for treatment of drug dependent persons who are able to live in their own homes in the community.

3. An education information center, which is an information center facility offering education and information to drug dependent persons, their families, and the general community, but which engages in no direct treatment. Such a center may make referrals to approved treatment facilities.

4. A communication center or rap house, which is a program oriented toward youth with the goal of prevention of drug dependency. Such a center may make referrals to appropriate treatment facilities.

5. A hot line, which is a telephone installed to respond to requests for information about drugs, drug treatment facilities, and emergency treatment centers.

6. A drug dispensing program, which is the scheduled dispensing or administering of drugs, including methadone, pursuant to a permit or license issued by an appropriate federal authority.

(b) "DATE center" shall not include the following:

1. "Nursing homes" or "homes" as that term is defined in s. 400.021(7).

2. Drug abuse education program established pursuant to s. 233.067.

(4) "Detoxification" means the administering of methadone or other drug in decreasing doses, pursuant to federal permit, as a substitute narcotic drug to reach a drug free state in a period not to exceed 21 days in order to withdraw an individual who is dependent on heroin or other morphine-like drugs from the use of these drugs.

(5) "Drug abuser" means a person who is so habitually dependent on the use of controlled substances as to have lost the power of self-control with respect to their use, and

(a) Who is dangerous to himself or others as a result of such abuse, or

(b) Whose judgment has been so impaired as a result of such abuse that he cannot rationally appreciate his need for care.

(6) "Treatment resource" means any licensed public or private facility, service, or program providing treatment or rehabilitation services for drug abusers, including, but not limited to, a residential rehabilitation center; a nonresidential day-care center; a community mental health center, clinic or program; or a drug-dispensing program.

(7) "Controlled substances" means the substances listed in the following subsections of s. 893.03:

(1) SCHEDULE I.—Paragraphs (a) and (b) and subparagraphs 1., 2., 3., 7., 8., 13., and 14. of paragraph (c).

(2) SCHEDULE II.—Subparagraphs 1., 2., and 3. of paragraph (a) and paragraphs (b) and (c).

(3) SCHEDULE III.—Paragraph (a).

(4) SCHEDULE IV.—Paragraphs (a), (f), (h), and (k).

History.—s. 1, ch. 70-183; s. 1, ch. 71-222; ss. 1, 4, 5, ch. 72-302; s. 1, ch. 73-154; s. 23, ch. 73-331; s. 1, ch. 74-172.

397.031 Duties of department.—The Department of Health and Rehabilitative Services, hereinafter referred to as "department," shall:

(1) Formulate a comprehensive plan for diagnosis, treatment, and education in the areas of drug abuse and dependence and revise such plan from time to time.

(2) Promote, develop, establish, coordinate, and conduct unified programs for education, prevention, diagnosis, treatment, and rehabilitation in the field of drug abuse and dependence and for cooperation with other federal, state, local, and private agencies.

(3) Provide public education and training and disseminate and gather information relating to drug abuse and dependency.

(4) Promote, develop, establish, coordinate, and conduct through the department or any approved agency, public or private, unified programs for education, prevention, diagnosis, research, treatment, aftercare, community referral, and rehabilitation in the field of drug abuse and dependency and, within the amount made available by appropriation, to implement and administer such programs.

(5) Permit, encourage, coordinate, and direct single and multiple programs for drug abuse treatment and education across division lines of authority to utilize the maximum resources of the department in the most efficient manner possible.

(6) Establish a funding program for the dissemination of available federal, state, and private funds to units of state or local government or private organizations which establish and implement approved local drug abuse education or treatment programs.

(7) Promulgate rules and regulations for the implementation of the authority and responsibilities within this chapter, and employ persons responsible for implementing the purposes of this chapter.

(8) Establish guidelines and provide for the systematic and comprehensive evaluation of the effectiveness of various programs licensed by the department.

History.—s. 2, ch. 70-183; s. 1, ch. 70-439; s. 2, ch. 71-222.

397.041 Hospital and outpatient facilities for drug dependents.—

(1) The department shall have the authority to designate facilities within the department to be used exclusively or partially for the treatment of drug dependents. These facilities may be operated as inpatient or outpatient programs.

(2) The department shall establish procedures whereby persons who are drug dependents may seek admission to these programs on a voluntary basis.

(3) The department shall have the authority to contract with other governmental or private agencies for additional treatment facilities or programs. The department is encouraged to establish these programs on a regional basis with emphasis on prevention and preventive education.

(4) Any person within the care or custody of any division of the department may be transferred for treatment to any program for hallucinogenic, barbiturate, or narcotic drug abuse problems approved by the department.

(5) No person who voluntarily enters any hospital or outpatient facility or program for treatment of drug dependency shall be retained in such facility or program against his will, nor shall such volunteer be confined in or assigned to any penal institution.

History.—s. 3, ch. 70-183; s. 1, ch. 70-439.

397.051 Applications for treatment of drug dependency.—

(1) Any drug dependent who wishes to submit himself for treatment and cure may apply to the department for admission to drug treatment programs operated or approved by the department.

(2) Drug dependents who submit themselves for voluntary treatment shall be admitted to programs within the financial and space capabilities of the department.

(3) The department shall establish a fee system for treatment and the fees shall be assessed in accordance with the person's ability to pay.

History.—s. 4, ch. 70-183; s. 1, ch. 70-439.

397.052 Involuntary treatment.—

(1) A person may be ordered to treatment at an appropriate treatment resource by the Circuit Court upon the petition of his spouse, a parent or guardian, any next of kin, a physician, the head of any state treatment facility or rehabilitation center, the sher-

iff of the county where such person resides or is found, or any three citizens of the state.

(a) The petition shall allege that the person:

1. Is a habitual abuser of controlled substances not pursuant to a lawful prescription;

2. Has lost the power of self control with respect to the use of such controlled substances; and

3. Has threatened, attempted, or actually inflicted, physical harm on himself or others, or is in need of medical treatment and care and, by reason of drug abuse, his judgment has been so impaired that he is incapable of appreciating his need for care and of making a rational decision in regard thereto. A mere refusal to undergo treatment shall not, however, by itself constitute evidence of lack of judgment with respect to the need for care.

(b) The petition shall be accompanied by a certificate of a physician and a certificate of a person possessing training and experience in drug abuse treatment and rehabilitation, said certificates to be based on an examination of the drug abuser made within 10 days prior to the filing of the petition. The certificates shall set forth their findings in support of the allegations of the petition. If the person whose treatment is sought has refused to submit to an examination, the fact of such refusal shall be alleged in the petition.

(2) Upon receipt of the petition, the court shall fix a date for a hearing on the issues no later than 10 days from the date the petition was received. The court shall give notice of the hearing to:

(a) The petitioner;

(b) The person whose treatment is sought, his next of kin other than the petitioner, and his parents or legal guardian, if he is a minor; and

(c) To any other person whose presence the court deems advisable.

Copies of the petition and certificate shall be delivered to all of the parties, together with the notice of hearing.

(3) At the hearing, the court shall hear all relevant testimony, including testimony of those providing certificates pursuant to subsection (1). The person whose treatment is sought shall be present unless the court has reason to believe that his presence is likely to be injurious to him; in this event, the court shall appoint a guardian ad litem to represent him throughout the proceeding. The court shall examine the person whose treatment is sought in open court or, if it is deemed advisable, out of court. If the person whose treatment is sought has refused to be examined, he shall be afforded an opportunity to consent to examination by a court-appointed physician and by a person possessing training and experience in drug abuse treatment and rehabilitation appointed by the court. If he refuses and there is sufficient evidence to believe that the allegations of the petition are likely to be true, or, in any case, if the court believes that more evidence is necessary, the court may preliminarily order the person to an appropriate treatment resource for a period of not more than 5 days for purposes of an examination. If, after hearing all relevant evidence, including the results of any case findings, the court finds that the grounds for court-ordered treatment have been met by clear and convincing proof, the court shall make a final order stating its findings and ordering the person to treatment at or through a treatment resource deemed appropriate by the court. Except in the case of a person who is ordered to treatment on the grounds that he is likely to inflict physical harm upon himself or others, the court shall not order a person's treatment unless there is sufficient evidence that an appropriate treatment resource is available.

(4) A person ordered to treatment pursuant to this section shall remain under the treatment designated by the court for a period of 30 days unless sooner discharged. At the end of the 30-day period, he shall automatically be discharged unless the treatment resource, prior to the expiration of such period, obtains renewal of the order for treatment upon the same grounds set forth in subsection (1) for a further period of 90 days unless sooner discharged. If a person has been ordered to treatment because he is a drug abuser who is likely to inflict physical harm on himself or others, the treatment resource shall apply for a renewal of the order to treatment unless such likelihood no longer exists.

(a) A person reordered to treatment, who has not been discharged by the treatment resource before the end of the 90-day period, shall automatically be discharged at the expiration of that period unless the treatment resource, prior to the expiration of such period, obtains a court order on the grounds set forth in subsection (1) for renewal of the order for treatment for a further period not to exceed 6 months.

(b) Upon receipt of a petition for renewal of the order for treatment, the court shall fix a date for hearing no later than 10 days from the date the petition was received. Notice of the application and the date of the hearing fixed by the court shall be served on:

1. The petitioner;

2. The person whose treatment is sought, his next of kin, and one of his parents or his legal guardian if he is a minor;

3. The original petitioner, if different from the petitioner for renewal of the order for treatment; and

4. Any other person whose presence the court deems advisable.

At the hearing the court shall proceed in the manner previously set forth herein.

(5) A person ordered to treatment in, and who is in the custody of, a treatment resource for care shall be discharged at any time prior to the end of the period for which he has been ordered to treatment when one of the following conditions are met:

(a) In the case of a drug abuser ordered to treatment on the grounds of likelihood of infliction of physical harm upon himself or others, when such likelihood no longer exists; or

(b) In the case of a drug abuser ordered to treatment on the grounds of need of treatment and care, accompanied by incapacity to make a determination respecting such need, either when such incapacity no longer exists or when it is evident that further treatment and care will not bring about further significant improvements in such person's condition.

(6) The person whose treatment is sought shall be informed of his right to contest the application, to be represented by counsel at every stage of proceedings relating to his order to treatment, and to have counsel appointed for him by the court, if he desires the assistance of counsel and is financially unable to obtain counsel. If the court believes that the person needs the assistance of counsel, the court shall appoint counsel for him regardless of his wishes. Further, the person for whom treatment is sought shall be informed of his right to be examined by a physician and a person of his choice who possesses training and experience in drug-abuse treatment and rehabilitation. If the person is financially unable to obtain such services and requests such examinations, the court shall provide payment for the required examinations.

(7) A person ordered to treatment under the provisions of this chapter may at any time seek to be discharged from treatment by writ of habeas corpus.

History.—s. 2, ch. 74-172.

397.053 Records of drug abusers.—

(1) The registration and other records of treatment resources, whether inpatient, intermediate, or outpatient, shall remain confidential, and information which has been entered in the records shall be considered confidential information.

(2) No part of the treatment records shall be disclosed without the consent of the person to whom it pertains, but appropriate disclosure may be made without consent to treatment personnel for use in connection with the treatment of such person and to counsel representing the person in any proceeding held pursuant to s. 397.052. Disclosure may also be made without consent upon court order for purposes unrelated to treatment after application showing good cause therefor. In determining whether there is good cause for disclosure, the court shall weigh the need for the information to be disclosed against the possible harm of disclosure to the person to whom such information pertains.

(3) Notwithstanding the provisions of this section, the secretary of the department or his designee may open patients' records for purposes of significant research into the causes and treatment of drug abuse. The secretary shall not open such records, however, unless application is made by a researcher or research agency of professional repute, and unless the need for the records and the significance of the research for which they are to be used has been demonstrated to his satisfaction. Records shall not be open under this subsection unless adequate assurances are given that patients' names and other identifying information will not be disclosed by the applicant.

History.—s. 2, ch. 74-172.

397.054 Visitation and communication of patients.—

(1) Subject to reasonable regulations regarding hours of visitation established by the division or by the agency in charge of a facility, drug abusers who are either voluntary or involuntary patients in any inpatient facility under this chapter shall be allowed opportunity for adequate consultation with counsel, and as much opportunity for continuing contact with family and friends as is consistent with an effective treatment program.

(2) The facility may make reasonable rules regarding the use of the telephone by patients and the receipt of mail and other communications by patients in such facilities.

History.—s. 2, ch. 74-172.

397.055 Payment for care.—

(1) Reasonable charges and expenses for the care, maintenance and treatment of drug abusers under any provision of this chapter may be made, and reimbursement for such charges and expenses that may be advanced by the state or any political subdivision thereof shall be a lawful charge against the person and estate or property, real, tangible, or intangible, of said person in this state. Such charges and expenses may lawfully be paid from the estate of said person by any authorized personal representative, parent, or legal guardian *[of] said person. However, the payment thereof, in advance or otherwise, shall never be a prerequisite to the care, maintenance, and treatment of any person under any circumstances whatsoever in a public facility. Any suit or action instituted by the state or any political subdivision thereof for the recovery of such charges and expenses against the person or his duly authorized personal representative, parent, or legal guardian shall be brought by the state attorney of the Judicial Circuit in which said person was ordered to treatment or by the Department of Legal Affairs or by both such State Attorney and Department of Legal Affairs.

(2) Notwithstanding any other provision to the contrary in this chapter, a private hospital or private facility, whether an outpatient or an inpatient unit, shall not be required to accept any person for treatment through court proceedings or otherwise.

(3) Any person assisted under this chapter or his responsible relatives may be required to contribute toward the cost of his subsistence, care, or treatment to the extent provided in applicable law and regulations. No person may be discriminated against on the basis of indigence.

History.—s. 2, ch. 74-172.
*Note.—"Of" substituted for "or" by the editors.

397.056 False information or lack of probable cause to secure an order to treatment; penalty.—

(1) Any person who knowingly furnishes false information for the purposes of securing an order to treatment for any person for the treatment of drug abuse is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2) Any person who, without probable cause for believing a person to be a drug abuser, causes or conspires with or assists another to cause any person to be ordered to treatment under this chapter, or causes or conspires with or assists another to cause the denial to any person of any right accorded to him under this chapter, is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(3) Any person who, without probable cause for believing a person to be a drug abuser, executes a

petition, application, or certificate pursuant to this chapter by which such individual causes or attempts to cause any person to be ordered to treatment is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

History.—s. 2, ch. 74-172.

397.057 Immunity from personal liability.—The administrator of any treatment resource acting pursuant to the provisions of this chapter shall be entitled to rely in good faith upon the recommendations made for admission by any individual, or any certification with respect to any individual, filed in conjunction with judicial proceedings for involuntary treatment of a drug abuser. All persons acting in good faith, reasonably, and without negligence in connection with the preparation or execution of petitions, applications, certificates, or other documents or the apprehension, detention, discharge, examination, transportation, or treatment of a person under the provisions of this chapter shall be free from all liability, civil or criminal, by reason of such acts.

History.—s. 2, ch. 74-172.

397.061 Department's cooperation with courts.—The department may, within its resources, cooperate with any court of proper jurisdiction in treating, counseling, examining, or otherwise aiding a person before the court with a narcotic, barbiturate, or hallucinogenic drug problem, or may aid the court with whatever resources are available in meeting whatever stipulations the court may make for probation of such individual.

History.—s. 5, ch. 70-183.

397.071 Program classification.—The department shall classify drug abuse programs according to character and range of services provided. Whenever it deems distinctions in its standards, rules, and regulations to be appropriate as among different classes of DATE centers, it may make such distinctions.

History.—s. 3, ch. 71-222.

397.081 License required.—

(1) It is unlawful to operate or maintain a DATE center without first being licensed by the department.

(2) With each application for license for a DATE center submitted to the department there shall be included a comprehensive outline of the proposed rehabilitative program.

History.—s. 3, ch. 71-222.

397.091 Expiration of license and renewal; regular and interim licenses.—

(1) A regular license issued for operation of a DATE center, unless sooner suspended or revoked, shall expire 12 months from the date of issue, unless the same shall have been renewed prior thereto for the next succeeding year. A license shall be renewed upon the filing of application for such renewal on forms prescribed by the department.

(2) Licensed operators against whom a revocation or suspension proceeding is pending at the time of license renewal shall be issued an interim license effective until final disposition by the department of such revocation proceedings. If the final order of the department is appealed from, the court before whom the appeal is taken may order the extension of the interim license for a period of time to be specified in said order.

(3) Interim licenses for not to exceed 90 days may be issued by the department to those applicants who have substantially complied with all the requirements for regular licensing and for which action has been initiated to satisfy all requirements. Interim licenses shall be renewed only in cases of extreme hardship and in which the failure to fully comply with the requirements was not caused by the applicant. The obligations of the interim licensee are the same as those of a regular licensee.

History.—s. 3, ch. 71-222; s. 2, ch. 73-154.

397.092 Refusal of license; renewal; revocation; notice; hearing.—

(1) No license shall be denied, revoked, or suspended except after notice in writing to the applicant or licensee setting forth the particular reasons for the proposed action and provision for a fair hearing, if demanded by the licensee or applicant. Such notice shall be effected by registered or certified mail with return receipt requested or by personal service. The licensee or applicant, within 10 days after receipt of said notice, may request in writing a hearing, by delivering the request to the department in person or by due course of mail. If no such request is made within the time fixed, the department shall proceed to deny, revoke, or suspend said license as set out in the notice of the proposed action.

(2) All hearings under this section shall be held by the department or any agent designated by it within the county in which the licensee or applicant operates or applies for license to operate a DATE center as defined in s. 397.021(3). A transcript of the proceedings shall be reviewed by the department, which shall enter its decision thereon.

(3) The procedure governing hearings authorized by this section shall be in accordance with rules promulgated by the department. The department or any agent designated by it may take testimony concerning any matter within its jurisdiction and may administer oaths for that purpose. The department or its agent shall have the power to issue summons and subpoenas for any witness and subpoenas duces tecum, which shall be served and returned as provided by law. At the hearing, the applicant or licensee shall have the right to cross-examine witnesses against him, to produce witnesses in his defense, and to appear personally or by counsel.

(4) On the basis of any such hearing, or upon the failure of the applicant or licensee to request a hearing, the department shall make a determination specifying its findings of fact and conclusions of law. A copy of such determination shall be sent by registered or certified mail or be personally served upon the applicant or licensee. The determination shall become final unless the applicant or licensee applies for a writ of certiorari in the circuit court of the county where the headquarters of the department is located, within the time and in the manner provided in the Florida Appellate Rules.

(5) A full and complete record shall be kept of all proceedings, and all testimony shall be reported but

need not be transcribed unless the decision is appealed. Copies of the transcription may be obtained by any interested party on payment of the cost of preparing such copies.

History.—s. 3, ch. 71-222.

cf.—s. 1.01 Defines registered mail to include certified mail with return receipt requested.

397.093 Procedure for reinstatement of revoked or suspended license.—

(1) When a license has been revoked or suspended, the licensee, if he has not previously had a license revoked or suspended under this chapter, may at any time after the determination has become final request a hearing for the purpose of showing that the reasons for the revocation or suspension of license have been corrected and that the license should be reinstated. No licensee who has previously had a license suspended or revoked under this chapter may request a hearing to reinstate the license prior to 1 year after the determination becomes final.

(2) The request for hearing shall be in writing and shall be delivered to the department in person or by due course of mail.

(3) Any hearing conducted under this section shall not operate to stay or supersede any decision revoking or suspending a license.

(4) Hearings conducted under this section shall be conducted in the same manner as provided in s. 397.092.

History.—s. 3, ch. 71-222.

397.094 Violations.—Any person establishing, conducting, managing, or operating any DATE center without proper license under this chapter shall be subject to injunctive proceedings to restrain and enjoin the operation of any DATE center in violation of the provisions hereof.

History.—s. 3D, ch. 71-222; s. 2, ch. 72-302.

397.095 Right of entry and inspection.—The department or any duly designated officer or employee thereof shall have the right to enter upon and into the premises of any DATE center licensed pursuant to this chapter at any reasonable time in order to determine the state of compliance with the provisions of this chapter and any rules and regulations in force pursuant thereto. Such right of entry and inspection shall also extend to any premises which the department has reason to believe is being operated or maintained as a DATE center without a license, but no such entry or inspection of any premises shall be made without the permission of the owner or person in charge thereof, unless a warrant is first obtained from the Circuit Court authorizing same. Any application for a DATE center license made pursuant to this chapter shall constitute permission for and complete acquiescence in any entry or inspection of the premises for which the license is sought in order to facilitate verification of the information submitted on or in connection with such application.

History.—s. 3, ch. 71-222.

397.096 Information confidential.—Information received by authorized persons employed by, or volunteering services to, a DATE center or received by the licensing agency through files, reports, inspection, or as otherwise authorized under this chapter shall be deemed privileged and confidential information and shall not be disclosed ~~publicly~~ in such a manner as to identify individuals, ~~or institution, except in a proceeding involving the question of licensure~~.

History.—s. 3, ch. 71-222; s. 3, ch. 72-302.

397.098 Drug dispensing programs; prohibitions.—Drug dispensing programs which do not provide supporting rehabilitative programs such as counseling, therapy, or vocational rehabilitation are prohibited and shall not be licensed as provided herein. Any violation of this provision shall be subject to injunctive proceedings in accordance with s. 397.094.

History.—s. 6, ch. 72-302; s. 4, ch. 73-154.

397.099 Removal of disabilities of minors in order to obtain rehabilitative or medical treatment.—The disability of nonage of minors is removed for the purpose of obtaining rehabilitative or medical treatment for drug abuse or dependency from a private physician licensed to practice medicine under chapter 458 or chapter 459 or a hospital, public clinic, or facility administered, authorized, or licensed by the Department of Health and Rehabilitative Services. Consent to treatment by a minor shall have the same force and effect as though it was executed by a person who has reached the legal age of majority. Any such consent shall not be subject to later disaffirmance by reason of minority.

History.—s. 7, ch. 72-302.

397.10 Legislative intent.—It is the intent of the Legislature to provide a meaningful alternative to criminal imprisonment for individuals capable of rehabilitation as useful citizens through techniques and programs not generally available in state or federal prison systems or programs operated by the [1][Department of Health and Rehabilitative Services.] It is the further intent of the legislature to encourage trial judges to use their discretion to refer persons charged with, or convicted of, violation of laws relating to drug abuse or violation of any law committed under the influence of a narcotic drug or medicine to a state-licensed drug rehabilitation program in lieu of, or in addition to, imposition of criminal penalties.

History.—s. 1, ch. 73-350.

[1]Note.—Bracketed language substituted for "Division of Youth Services." See s. 3, ch. 75-48.

397.11 Definitions.—As used in ss. 397.10-397.20:

(1) "Drug rehabilitation program" means a drug rehabilitation program licensed under the provisions of this chapter.

(2) "Department" means the Department of Health and Rehabilitative Services.

History.—s. 2, ch. 73-350.

397.12 Reference to drug abuse program.—When any person, including any juvenile, has been charged with or convicted of a violation of any provision of chapter 893, or of a violation of any law committed under the influence of a controlled substance, the court, [1][Department of Health and Rehabili-

CHAPTER 76-132

Senate Bill No. 311

AN ACT relating to confidentiality of information with respect to the rehabilitation of drug dependents; amending s. 397.096, Florida Statutes; prohibiting disclosure in a manner as to identify individuals; removing the prohibition against disclosure in a manner as to identify treatment facilities; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 397.096, Florida Statutes, is amended to read:

397.096 Information confidential.--Information received by authorized persons employed by, or volunteering services to, a DATE center or received by the licensing agency through files, reports, inspection, or as otherwise authorized under this chapter shall be deemed privileged and confidential information and shall not be disclosed ~~publicly~~ in such a manner as to identify individuals ~~or facilities except in a proceeding involving the question of licensure~~.

Section 2. This act shall take effect upon becoming a law.

Approved by the Governor June 15, 1976.

Filed in Office Secretary of State June 16, 1976.

This public document was promulgated at a base cost of $9.86 per page for 1,200 copies or $.0082 per single page for the purpose of informing the public of Acts passed by the Legislature.

CODING: Words in ~~struck-through~~ type are deletions from existing law; words in underscored type are additions.

STATE OF FLORIDA

DEPARTMENT OF
Health & Rehabilitative Services

Reubin O'D Askew, Governor

1317 WINEWOOD BOULEVARD TALLAHASSEE, FLORIDA 32301

March 17, 1978

Ms. Chris English
Office of the Governor
State of Florida
Tallahassee, FL 32301

Dear Ms. English:

Per your request today I am forwarding a copy of the Scope and Conclusions and Action Required and Recommendation on Project Straight, Inc., a licensed drug treatment program in St. Petersburg. Mr. Ron Brown, on the Secretary's Executive staff requested that I forward a copy of the report to you as quickly as possible.

District V staff performed the investigation and Mr. Harry Moffett of my staff provided consultation on the final report.

If you have any further questions please contact me.

Very truly yours,

PETER B.C.B. IVORY, M.D.
Mental Health Program Staff Director

Copy to: Alvin J. Taylor
Jacquelyne A. Gallop
Frank D. Nelson
Harry W. Moffett
Lucy Hadi-HRS District V, Acting Administrator
James Holley-HRS District V, MHP Specialist

recovery proceedings. In addition, only a relatively small sum remains to be drawn down by your agency and the subgrant award expires in a few weeks. After expiration of a subgrant award, your agency would only be required to maintain financial records for three years. Programmatic concerns could probably not be raised after the expiration of the project.

This continuing review of your project stems primarily from four sources, not in order of significance:

1. Newspaper articles by Mr. William Nottingham, St. Petersburg Times;

2. A written complaint by Mr. George A. Stevenson to Governor Reubin Askew;

3. Specific time-based programmatic modifications required by the Department of Health and Rehabilitative Services; and

4. Unresolved questions identified in an on-site monitoring by the Bureau and involving (a) alleged nepotism and (b) minority representation among clients and staff.

I would like to clearly state that we do not have, at this time, any evidence indicating any violation of Florida law, nor do we have any evidence clearly substantiating any violation of LEAA rules and regulations or standard subgrant conditions. What we have are unsubstantiated allegations and some legitimate questions coupled with an unfortunate time period.

The Bureau of Criminal Justice Planning and Assistance is eager to resolve all of the pertinent matters of concern so that the very important services provided by your project can continue on uninterrupted, and not under any continuing cloud of suspicion.

It is my complete expectation that all of these items will be resolved satisfactorily by the end of this month.

Sincerely,

Charles R. Davoli
Bureau Chief

CRD/JHD/mvs

cc: Mr. Frank Griffin, Pinellas MPU
Mr. J. B. Holley, District 5, DHRS
Ms. Chris English, Office of the Governor
Control: 76-A4-13-ER01

R.D. 4, Box 350
Georgetown, Delaware 19947
March 11, 1978

The Honorable Reubin Askew
Governor, State of Florida
Tallahassee, Florida

Dear Governor Askew:

Upon learning that two of my daughters, Gail and Kathy, ages 18 and 16, had been committed to the program known as Straight, Inc. by their mother and stepfather, I began attempts to determine what problem, if any, my daughters had, and whether Straight, Inc. offered satisfactory treatment.

Articles relating to Straight, Inc. were forwarded to me by the St. Petersburg Times at my request. These articles offered sworn statements from former counselors, HRS investigations, etc., as can be seen from the enclosed photocopies. My concern for the welfare of my daughters was greatly increased after reading these articles.

At the same time I requested these articles from the St. Petersburg Times, I wrote to the director of Straight, Inc., Mr. William Hartz, setting forth questions regarding the program. I asked that the program be explained to me--for instance, why parents could not see their child except in the presence of others, why they could not receive or send mail, etc. To date I have not had the courtesy of a reply.

Gail tried to run away twice, the last time being around February 3, 1978. Another daughter of mine, Brenda, age 19, was finally allowed to talk with her sister because she (Brenda) was "stirring up too much trouble." Brenda, being very close to her sister, feels as I do--this program is no place for either Kathy or Gail. She felt that Gail, in just three short weeks, did not sound like herself, almost like she had been programed, like she had been brainwashed. I might add that Brenda was allowed to see Gail only with her mother and stepfather present, the director, Mr. Hartz, and the whole conversation was recorded.

On March 4, 1978, I called Straight, Inc. and spoke with an Ed Drizzle, explained that I was calling long distance, that two of my daughters were in the program and that I would like to speak with them. In the event they were not there at that time, I asked that the girls be allowed to return my call. He was one of the rudest people I have ever talked with--rude to the point of hanging up on me. If this is the type of people Straight, Inc. has for counselors, it only tends to confirm my fears that Straight, Inc. is not a place I want my daughters in.

It is my belief that the tactics used by Straight, Inc. are damaging. The problem my girls experienced should have been handled at home through love and understanding. I strongly disagree with a program that uses

"'time out,' known by some clients as solitary confinement, 'running,' where juveniles are exercised--forcibly if necessary, and 'marathon sessions' known to some clients as 'come downs' where a group of counselors will yell remarks designed to provoke the client into feeling guilty" (quoted from the St. Petersburg Times, Sunday, December 4, 1977).

I would urge that an investigation be conducted into the program offered by Straight, Inc. Not only am I concerned with the program offered, but the fact that my daughter, Gail, was to graduate from school this spring and cannot now do so since no schooling is offered by Straight, Inc. I do not feel her problem warrants such drastic action as has been taken. She is being denied her education and I can't help but wonder what her mental attitude toward life will be after being in the Straight, Inc. program.

Your consideration in this matter will be greatly appreciated.

Very truly yours,

George E. Stevenson

George E. Stevenson

cc: C.B.S.--60 Minutes
Robert G. Marshall, Director
Health & Rehabilitative Services
Mr. William Nottingham, Staff Writer
St. Petersburg Times
Secretary of Health, Education & Welfare
Attention: Ms. Backus
John H. Dale, Jr., Assistant Chief
Bureau of Criminal Justice Planning & Assistance
Director, National Institute of Drug Abuse

The Florida Department of Administration

DIVISION OF STATE PLANNING
530 CARLTON BUILDING, TALLAHASSEE, FLORIDA 32304 - TELEPHONE (904) 488-6001
BUREAU OF CRIMINAL JUSTICE PLANNING & ASSISTANCE

R. G. Whittle, Jr.
STATE PLANNING DIRECTOR

Reubin O'D. Askew
GOVERNOR

Wallace W. Henderson
SECRETARY OF ADMINISTRATION

March 20, 1978

Mr. George E. Stevenson
R.D. 4, Box 350
Georgetown, Delaware 19947

Dear Mr. Stevenson:

Thank you for copying Dr. John H. Dale, Jr. with your letter of March 11, 1978, to Governor Reubin Askew.

The Bureau of Criminal Justice Planning and Assistance is conducting both a financial and programmatic assessment of "Straight, Inc."

A report will be issued in the next few weeks outlining all of our findings. A copy of this report will be made available to the Florida Department of Health and Rehabilitative Services, which is responsible for licensing all drug abuse treatment programs within the State.

Any indication of serious impropriety or possible illegal activity would, as a matter of standard procedure, be turned over to the proper local law enforcement officials. This is not to imply that any such situation is, in fact, evident at this time.

If I can provide you with any additional information, please let me know.

Sincerely,

Charles R. Davoli
Bureau Chief

CRD/JHD/mvs

cc: Ms. Chris English, Office of the Governor
Mr. Harry Moffett, DHRS - Drug Abuse
Mr. Frank Griffin, Director, Pinellas MPU
Mr. James E. Hartz, Project Straight, Inc.
Control: 76-A4-13-EB01

STRAIGHT, INC.

JAMES E. HARTZ
EXECUTIVE DIRECTOR

(A NON-PROFIT CORPORATION)

POST OFFICE BOX 40052
St. Petersburg, Florida 33743
Phone: (813)541-6666

May 2, 1978

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Mr. George Stevenson
R. D. 4, Box 350
Georgetown, Deleware 19947

Dear Mr. Stevenson:

I am in receipt of your personal handwritten letter and your letter to Governor Askew. I can appreciate your concern for the future of your daughters. Enclosed please find a brochure which will describe the program in a little more detail. Also enclosed for your review is the recent evaluation of our program by an independent professional in the field. This evaluation is required by our small L.E.A.A. grant.

We certainly want you to feel free to journey to St. Petersburg and see the program in action for yourself. We would be glad to have you. After reviewing many of the more traditional therapeutic modalities that deal with this problem, I can only say that this is the most exciting, positive and successful therapeutic system I have observed. Should you not be able to come to Florida, I would be glad to talk with you by phone. I feel a phone conversation can not give the information that an on-site visit would, but I will try to explain any questions you may have if you can not visit.

Thank you for your concern.

Sincerely,

James E. Hartz
Executive Director
STRAIGHT, INC.

JEH:mga

cc: Governor R. Askew
Dr. John Dale