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PART IV

DEPARTMENT OF HEALTH, EDUCATION, AND

Public Health Service

■

CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

General Provisions

Title 42—Public Health

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL PROVISIONS

PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

On May 9, 1975, the Department of Health, Education, and Welfare and the Special Action Office for Drug Abuse Prevention published in the FEDERAL REGISTER (40 FR 20522) a notice of proposed joint rulemaking setting forth a proposed new Part 2 of Title 42 of the Code of Federal Regulations governing the confidentiality of alcohol and drug abuse patient records.

Interested persons mere invited to submit written comments, views, or arguments with respect to the proposed regulations within 30 days of the date of publication of that notice. All comments so submitted were carefully considered, and at various stages in the rulemaking process, the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected by the proposed regulations were consulted.

As finally adopted and set forth hereinafter, the regulations contain two major substantive changes from the May 9 proposal. The separate treatment of funding sources and third-party payers (§§ 2.21 and 2.37 of the proposed regulations) was abandoned as unworkable, primarily because the prohibitions which the proposed regulations would have placed on funding sources would have directly conflicted with requirements which have been proposed in implementation of Title XX of the Social Security Act (see Proposed 45 CFR 228.63, 40 FR 16802, 16809, April 14, 1975). In lieu of this approach, § 2.37 has been revised to provide that funding sources and third-party payers maintaining drug or alcohol abuse patient records are subject to restrictions upon disclosure to the same extent and in the same manner as any other entity maintaining records which are within, the scope of the authorizing legislation and this Part.

The other major change is in the area of criminal justice system referrals, and the grounds for the rules finally adopted are set forth in the basis and purpose section (§ 2.39–1) pertaining thereto. In connection with that change, it must be frankly acknowledged that the arguments set forth in the corresponding basis and purpose section (§ 2.40–1) of the May 9 proposal have merit. The final rule may in certain instances result in a compromise of the treatment process, if judges or other authorities in the criminal justice system overreact to information whose communication is allowed under the final rules but would have been prohibited under the proposed rules.

Against such an adverse effect, however, there must be weighed the very real advantage which genuine cooperation between community social service systems and the criminal justice system can yield for those whose lives are crippled and scarred by the consequences of their own criminal conduct. Governmental responses based on a pure medical model have not met with noticeably greater success than those based on a purely punitive approach, and it mould be tragic if these rules were so constructed as to become a barrier to the development of better ways to deal with those who are caught up in a pattern of seriously antisocial behavior.

In addition to the foregoing major changes, the following minor policy changes were made.

Provisions relating to destruction or other disposition of records were dropped from § 2.21 (§ 2.22 in the May 9 proposal) as unnecessary except in the case of programs discontinuing operations.

The fixed limitation on the permissible duration of written consent for disclosure was dropped from § 2.31 in favor of a limitation to such duration as may be reasonably necessary to effectuate the purpose for which the consent is given.

The specification of crimes in § 2.65 for which a court order may be granted authorizing use of program records in the investigation or prosecution of a patient was broadened to cover any "extremely serious" crime, with those listed in the May 9 notice being retained as examples.

Finally, a number of clarifying, technical, and conforming changes were made in the May 9 proposal, but these are without significant substantive effect.

Accordingly, pursuant to the authority of section 408 of the Drug Abuse Office and Treatment Act of 1972, as amended by Pub. L. 92–282 (21 U.S.C. 1175), and section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, as amended by Pub. L. 93–282 (42 U.S.C. 4582), and under the authority delegated to the General Counsel of the Special Action Office for Drug Abuse Prevention (39 FR 17901, May 21, 1974), Subchapter A of Chapter I, Title 42, Code of Federal Regulations, is amended by inserting immediately after Part 1 thereof a new Part 2 to read as set forth below.

Effective date. These regulations shall be effective on August 1, 1975.

Dated: June 25, 1975.

R. MOURE,
Acting Assistant Secretary for Health, Department of Health, Education, and Welfare.

Approved: June 26, 1975.

CASPAR W. WEINBERGER,
Secretary of Health, Education, and Welfare.

Dated: June 27, 1975.

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

Dated: June 27, 1975.

ROBERT L. DUPONT,
Director, Special Action Office for Drug Abuse Prevention.

Subpart A—Introductory Statement

Subpart B—General Provisions

Subpart C—Disclosures With Patient's Consent

Subpart A—Introductory Statement

§ 2.1 Statutory authority—drug abuse.

(a) *Statutory provisions effective May 14, 1974.* Insofar as the provisions of this part pertain to any program or activity relating to drug abuse education, training, treatment, rehabilitation, or research, such provisions are authorized under section 408 of Pub. L. 92–255, the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1175) as amended by section 303 of Pub. L. 93–282 (88 Stat. 137). That section reads as follows:

§ 408. Confidentiality of patient records.

(a) Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (c), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) (1) The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).

(2) Whether or not the patient, with respect to whom any given record referred to in subsectlon (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) 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.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. 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. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(a) Except as authorized by a court order granted under subsection (b) (2) (C) of this section, no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

(f) Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than 8500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) The Director of the Special Action Office for Drug Abuse Prevention, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope or orders under subsection (b) (2) (C), as in the judgment of the Director are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(b) *Amendments effective June 30, 1975.* Effective on the date specified in section 104 of the Drug Abuse Office and Treatment Act of 1972 (June 30, 1975), the first sentence of section 408(g) above, will be amended by striking "Director of the Special Action Office for Drug Abuse Prevention" and inserting in lieu thereof "Secretary of Health, Education, and Welfare", and the second sentence of such section will be amended by striking "Director" and inserting "Secretary" in lieu thereof. Also effective on that date, section 408, above, will be further amended by (1) striking out "The" and inserting in lieu thereof "Except as provided in subsection (h) of this section, the" in the first sentence of subsection (g) of such section; and (2) adding at the end of such section the following new subsection:

(h) The Administrator of Veterans' Affairs, through the Chief Medical Director, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations established by the Secretary under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical cervices under such title 38 to veterans suffering from drug abuse. In prescribing and implementing regulations pursuant to this subsection, the Administrator shall, from thime to time, consult with the Secretary in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

§ 2.2 Statutory authority—alcohol abuse.

Insofar as the provisions of this part pertain to any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, such provisions are authorized under section 333 of Pub. L. 91–616, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (42 U.S.C. 4582), as amended by section 122(a) of Pub. L. 93–282, the Comprehesive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974 (88 Stat. 131). As so amended, that section reads as follows:

CONFIDENTIALITY OF RECORDS

Sec. 333. (a) Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) (1) The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).

(a) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) 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.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. 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. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Except as authorized by a court order granted under subsection (b) (2) (C) of this section, no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) The prohibitions or this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

(f) Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b) (2) (C), as in the judgment or the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith,

(h) The Administrator of Veterans' Affairs, through the Chief Medical Director, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations prescribed by the Secretary under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from alcohol abuse or alcoholism. In prescribing and implementing regulations pursuant to this subsection, the Administrator shall, from time to time, consult with the Secretary in order to achieve the maximum possible coordination or the regulations, and the implementation thereof, which they each prescribe.

§ 2.3 Previous regulations as controlling authority.

Attention is called to the interpretative regulations, issued by the Special Action Office for Drug Abuse Prevention (37 FR 24636, November 17, 1972, as revised 38 FR 33744, December 6, 1973, referred to hereinafter in this part as the "previous regulations"). Those regulations have been given a special status as controlling authority by the provisions of section 303(d) of Pub. L. 93–282, as well as the references in the legislative history of that act to the precedents established under section 408 of Pub. L. 92–255. Such references appear at page 11 of House Committee Report No. 93–759 and at page H3563 of the Congressional Record for May 6, 1974. The latter citation is to a detailed analysis of the bill in its final form which was submitted for the Record by its floor manager, Chairman Staggers of the Interstate and Foreign Commerce Committee, when the bill was up for final action by the House of Representatives.

§ 2.4 General purposes.

(a) *Policy objectives.* The purpose of the regulations set forth in this part is to implement the authorizing legislation in a manner that, to the extent practicable, takes into account two streams of legal thought and social policy. One has to do with enhancing the quality and attractiveness of treatment systems. The other is concerned with the interests of patients as citizens, most particularly in regard to protecting their rights of privacy. Within each stream there are cross-currents, and it should come as no surprise that areas of turbulence are to be found at their confluence.

(b) *Limited purpose.* The regulations contained in this part are not intended to direct the manner in which substantive functions, such as research, treatment, and evaluation, should be carried out, but rather to define the minimum requirements for the protection of confidentiality of patient records which must be satisfied in connection with the conduct of those functions in order to carry out the purposes of the authorizing legislation. This does not mean that observance of only the minimum legal requirements is always the wisest course, but in framing these regulations, allowance has necessarily been made for a diversity of emphasis and approach in the many different jurisdictions and by the great variety of public and private agencies which must find a way to function within the limits here prescribed.

§ 2.5 Format.

(a) *Basis and purpose sections.* Each section setting forth rules on any given topic in Subparts B through E of this part is followed by a section setting forth their basis and purpose. In many cases, the basis and purpose section is itself an interpretative rule regarding the legal authority of the rulemakers. In other instances, it summarizes historical or evidentiary material relevant to the validity and interpretation of the section which precedes it.

(b) Statutory rules fully incorporated. Although, for convenience of reference, the statutory basis for this part is set out in full in §§ 2.1 and 2.2, the regulations in Subparts B through E of this part are intended to include all of the operative statutory provisions.

§ 2.6 Administration and enforcement in general.

It is not contemplated that any particular agency will be set up specifically to enforce compliance with this part. Program which receive Federal grants may be monitored for compliance with this and other applicable Federal law as an incident to the grant administration process. Similarly, FDA inspections of methadone programs will include inspection for compliance with this part, which is incorporated by reference in the methadone regulation (21 CFR 310.505).

§ 2.7 Reports of violations.

Any violation may be reported to the United States Attorney for the judicial district in which the violation occurs. Violations on the part of methadone programs may be reported to the regional offices of the Food and Drug Administration. Violations on the part of a Federal grantee or contractor may be reported to the Federal agency monitoring the grant or contract.

Subpart B—General Provisions

§ 2.11 Definitions and usages.—Rules.

(a) *Authorizing legislation.* The term "authorizing legislation" means section 408 of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1175) and section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582), as such sections may be amended and in effect from time to time.

(b) *Construction of terms.* The dofinitions and rules of construction set forth in this section are applicable for the purposes of this part. To the extent that they refer to terms used in the authorizing legislation, they are also applicable for the purposes of such legislation.

(c) *Alcohol abuse.* The term "alcohol abuse" includes alcoholism.

(d) *Drug abuse.* The term "drug abuse" includes drug addiction.

(e) *Diagnosis and treatment.* The terms "diagnosis" and "treatment" include interviewing, counselling, and any other services or activities carried on for the purpose of or as an incident to diagnosis, treatment, or rehabilitation with respect to drug abuse or alcohol abuse, whether or not conducted by a member of the medical profession.

(f) *Program.*

(1) The term "program", when referring to an individual or organization, means either an individual or an organization furnishing diagnosis, treatment, or referral for alcohol abuse or drug abuse.

(2) The term "program", when not used in the sense defined in paragraph (f) (1), means a plan or procedure, whether functional or organizational, and whether or not governmental, for dealing with alcohol abuse or drug abuse problems from either an individual or a social standpoint.

(g) *Program evaluation.*

The term "program evaluation" means an evaluation of—

(1) The effectiveness, efficiency, compliance with applicable therapeutic, legal, or other standards, or other aspects of the performance, of a program as defined in paragraph (f) (1) of this section, or

(2) The validity, effectiveness, efficiency, practicability, or other aspects of the utility or success of a program in the sense defined in paragraph (f) (2) of this section.

(h) *Program director.* The term "program director" in the case of a program which is an individual means that individual, and in the case of a program which is an organization, the individual, if any, who is the principal, or, in the case of organizations consisting of partners or under the control of a board of directors, board of trustees or other governing body, the individual designated as program director, managing director, or otherwise vested with executive authority with respect to the organization.

(i) *Patient.* The term "Patient" means any individual (whether referred to as a patient, client, or otherwise) who has applied for or been given diagnosis or treatment for drug abuse or alcohol abuse and includes any individual who, after arrest on a criminal charge, is interviewed and/or tested in connection with drug or alcohol abuse preliminary to a determination as to eligibility to participate in a treatment or rehabilitation program.

(j) *Patient identifying information.* The term "patient identifying information" means the name, address, social security number, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a patient identifying number assigned by a program.

(k) *Alcohol abuse or drug abuse prevention function.* The term "alcohol abuse or drug abuse prevention function" means any program or activity relating to alcohol abuse or drug abuse education, training, treatment, rehabilitation, or research, and includes any such function even when performed by an organization whose primary mission is in the field of law enforcement or is unrelated to alcohol or drugs.

(l) The term "person" means an individual, a partnership, a corporation, a trust, a Federal or State governmental agency, or any other legally cognizable entity.

(m) *Service organization.* The term "service organization" means a person which provides services to a program such as data processing, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services.

(n) *Qualified service organization.* The term "qualified service organization" means a service organization which has entered into a written agreement with a program pursuant to which the service organization—

(1) acknowledges that in receiving, storing, processing, or otherwise dealing with any information from the program about patients in the program, it is fully bound by the provisions of this part;

(2) undertakes to institute appropriate procedures for safeguarding such information, with particular reference to patient identifying information; and

(3) undertakes to resist in judicial proceedings any efforts to obtain access to information pertaining to patients otherwise than as expressly provided for in this part.

(o) *Records.* The term "records" includes any information, whether recorded or not, relating to a patient, received or acquired in connection with the performance of any alcohol abuse or drug abuse prevention function, whether such receipt or acquisition is by a program, a qualified service organization, or any other person.

(p) *Communications not constituting disclosure.* The following types of communications do not constitute disclosures of records:

(1) Communications or information within a program between or among personnel having a need for such information in connection with their duties.

(2) Communications between a program and a qualified service organization of information needed by the organization to perform its services to the program.

(3) Communications of information which includes neither patient identifying information nor identifying numbers assigned by the program to patients.

(q) *Previous regulations.* The term "previous regulations" refers to the interpretative regulations issued by the Special Action Office for Drug Abuse Prevention, originally published November 17, 1972, 37 FR 24636, as revised December 6, 1973, 38 FR 33744.

(r) *State law.* The term "State law" refers to the law of a State or other jurisdiction, such as the District of Columbia, as distinguished from Federal law in general. As applied to transactions which do not take place in any State or other similar jurisdiction, the term refers to Federal common law as modified by any applicable Federal statutes and regulations.

(s) *Third party payer.* The term "third party payer" means any organization (or person acting as agent or trustee for an organization or fund) which pays or agrees to pay for diagnosis or treatment furnished or to be furnished to a particular individual, where such payment or agreement to pay is on the basis of an individual relationship between the payer and the patient (or a member of the patient's family in the case of self-and-family insurance coverage or similar arrangements) evidenced by a contract, an insurance policy, a certificate of membership or participation, or similar documentation.

(t) *Funding source.* The term "funding source" means any individual or any public or private organization, including any Federal, State, or local governmental agency, which makes payments in support of a program. A funding source is not, as such, a third party payer, even where its payment sare based directly or indirectly on the program's patient load with or without respect to specified categories of eligible persons.

(u) *August 22, 1974 draft.* References to the "August 22, 1974 draft" are to the draft regulations set out in the Advance Notice of Proposed Joint Rulemaking published in the FEDERAL REGISTER on August 22, 1974, 39 FR 30426, by the Department of Health, Education, and Welfare and the Special Action Office for Drug Abuse Prevention.

§ 2.11–1 Definitions and usages.—Basis and purpose.

(a) *In general.* The definitions are based upon the legislative history of and experience with the authorizing legislation, and are intended as aids to construing the provisions of this part to carry out the purposes of those statutes.

(b) *Coverage of applicants for treatment.* Section 2.11(i) is intended to make it clear that records of the identity and other information about a person whose application is rejected or withdrawn are fully as much covered by this part as records pertaining to a patient actually accepted for treatment.

(c) *Program terminology for patients not controlling.* While many programs prefer to use "client" or some other term instead of "patient" to describe the recipients of their services, it is believed preferable to use terminology in this part which is consistent with that used in the authorizing legislation. It should be clearly understood, however, that the records of any individual who fits the definition set forth in §2.11(i) are covered, no matter what terminology the program may use to designate his status.

(d) *Origin of "prevention function" terminology.* The definition of alcohol abuse or drug abuse prevention function in § 2.11(k) is adapted from the definition of drug abuse prevention function in section 103(b) of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1103(b)). Although there was no corresponding defined term available to the draftsman of the 1974 amendment to section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582), it is clear from the legislative history that the coverage of alcohol abuse patient records was intended to be fully as wide as the coverage of drug abuse patient records, and the definition in § 2.11(k) reflects that intention.

(e) Ambiguity of the term "program". It is recognized that it is ordinarily poor drafting technique to use the same term

in senses which are as different, yet related, as those in §§ 2.11 (f) (1) and 2.11(f) (2). This part, however, has to be read both in conjunction with the Food and Drug Administration's Methadone Regulation and the Drug Abuse Office and Treatment Act of 1972. The Methadone Regulation (21 CFR 310.505) clearly uses the term "program" in the § 2.11(f)(1) sense. In section 103(b) of the Act (21 U.S.C. 1103(b)), it is clearly used in the § 2.11 (f) (2) sense, and the usage in section 408(b)(2)(B) of the Act has from its original enactment been administratively interpreted to include both senses. As used in this part, the context should indicate the intended meanings with sufficient clarity to make this preferable to creating and defining new terminology which would be different from that used in related regulations and the authorizing legislation.

(f) *Construction of disclosures.* Section 2.11(p) is intended to clarify the status of communications which are carried on within a program or between a program and persons or organizations which are assisting it in providing patient care. The authorizing legislation was not intended to prohibit programs from carrying on accepted practices in terms of obtaining specialized services from outside organizations. In conjunction with the definition of qualified service organizations, set forth in § 2.11(n), the provisions of §2.11(p) should prevent the development; of abuses in this area.

§ 2.12 Applicability.—Rules.

(a) *In general.* Except as provided in paragraph (b) of this section, this part applies to records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any alcohol abuse or drug abuse prevention function—

(1) Which is conducted in whole or in part, whether directly or by grant, contract, or otherwise, by any department or agency of the United States.

(2) For the lawful conduct of which in whole or part any license, registration, application, or other authorization is required to be granted or approved by any department or agency of the United States,

(3) Which is assisted by funds supplied by any department or agency of the United States, whether directly through a grant, contract, or otherwise, or indirectly by funds supplied to a State or local government unit through the medium of contracts, grants of any description, general or special revenue sharing, or otherwise, or

(4) Which is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program conducting such function, or by a way of a tax-exempt status for such program.

(b) *Armed Forces and Veterans' Administration.*

(1) The Provisions of this part do not apply to any interchange, entirely within the Armed Forces, within those components of the Veterans' Administration furnishing health care to veterans, or between such components and the Armed Forces, of records pertaining to a person relating to a period when such person is or was subject to the Uniform Code of Military Justice.

(2) Except as provided in paragraph (b) (1) of this section, this part applies to any communication between any person outside the Armed Forces and any person within the Armed Forces.

(3) Except as provided in paragraph (b) (1) of this section, this part applies, insofar as it pertains to any drug abuse prevention function, to any communication between any person outside those components of the Veterans' Administration furnishing health care to veterans and any person within such components, until such date as the Secretary of Health, Education and Welfare exercises his authority (conferred by an amendment effective June 30, 1975) to prescribe regulations under section 408 of Pub. L. 92–255 (21 U.S.C. 1175). After such date, this part applies thereto to such extent as the Administrator of Veterans' Affairs, through the chief Medical Director, by regulation makes the provisions of this part applicable thereto.

(4) Except as provided in paragraph (b) (1) of this section, this part applies, insofar as it pertains to any alcohol abuse prevention function, to any communication between any person outside those components of the Veterans' Administration furnishing health care to veterans and any person within such components, to such extent as the Administrator of Veterans' Affairs, through the Chief Medical Director, by regulation makes the provisions of this part applicable thereto.

(c) *Period covered as affecting applicability.* The provisions of this part apply to records of identity, diagnosis, prognosis, or treatment pertaining to any given individual maintained over any period of time which, irrespective of when it begins, does not end before March 21, 1972, in the case of diagnosis or treatment for drug abuse or before May 14, 1974, in the case of diagnosis or treatment for alcohol abuse.

(d) Applicability determined by nature and purpose of records. The applicability of the provisions of this part is determined by the nature and purpose of the records in question, and not by the status or primary functional capacity of the recordkeeper.

§ 2.12–1 Applicability.—Basis and purpose.

(a) The broad coverage provided by § 2.12(a) is appropriate in the light of the remedial purposes of the statutes as well as the practical desirability of certainty and uniformity. Sections 2.12(a) (1) and 2.12(a) (2) simply follow the terms of subsection (a) of the statutes, with some explanatory material for the sake of clarity and explicitness.

(b) Sections 2.12(a) (3) and 2.12(a) (4) are based upon the use by Congress of the phrase "directly or indirectly assisted by any department or agency of the United States". In the light of the multiplicity and extent of Federal programs and policies which can be of assistance to drug and alcoholism programs, this wording strongly suggests an intention to provide the broadest coverage consistent with the literal terms of the statutes. Many programs commence with direct Federal assistance, financial, technical, or both, and later continue with State aid and private, tax-deductible contributions. It would be manifestly contrary to the general policy sought to be effectuated by the legislation if the confidential status of a program's records were to terminate, or even be called into question, by the cessation of direct Federal assistance.

(c) With regard to § 212 (a) (3), it seems clear that whenever a State or local government is assisted by the Federal government by may of revenue sharing or other unrestricted grants, all of the programs and activities of the State or local government are thereby indirectly assisted, and thus meet that aspect of the statutory criteria for coverage.

(d) Section 2.12 (a) (4) follows the doctrine established in *McGlotten v. Connally,* 338 F. Supp. 448 (D.C. D.C., 1972), in which it was held that the deductible status of contributions to an organization constitutes "Federal financial assistance" within the meaning of section 601 of the, 1964 Civil Rights Act (42 U.S.C. 2000d). The inclusion of the adjective "indirect" as a modifier of the term "assistance" as used in the provisions of law authorizing this part suggests an intention to provide coverage at least as broad, if not broader than, section 601 of the Civil Rights Act in respect of financial assistance. See, also, *Green v. Connally* 330 F. Supp. 1150 (D.C. D.C., 1971) aff'd sub. nom. *Coit v Green,* 404 U.S. 997, 92 S. Ct. 564, 30 L. Ed. 2d 550 (1971).

(e) Section 2.12(b) essentially repeats the interpretation given in § 1401.02(b) of the previous regulation except that it takes account of the special provisions inserted in the new law with reference to the Veterans Administration, and makes clear that the exemption for communications within the military–VA system does not generally apply to records pertaining to civilians.

(f) Section 2.12(c), which deals with the question of how the period covered by any given set of records affects the applicability of these regulations to them, restates the principle set forth in § 1401.–02(a) of the previous regulations, and applies it to records in the field of alcohol abuse as well as drug abuse. The authorizing legislation contains no effective date provisions. A construction which would apply the statutes to records of completely closed treatment episodes, records necessarily made and maintained prior to the enactment of the legislation, would create serious administrative problems. It seems doubtful, in any case, whether such records have been "maintained," within the meaning of the statutes, during any period of time after their enactment. On the other hand, if

treatment is actually carried on after the enactment of the applicable statute, then all the records should be covered irrespective of when treatment was begun, because such records clearly are being "maintained" after the enactment of the legislation.

(g) Section 2.12(d) has been included to make explicit one of the legal implications of the authorizing legislation, which is cast in terms descriptive of the records which are to be confidential rather than of the recordkeepers on whom a duty is thus imposed. The result is that, for example, where a State agency maintains an individual client record which contains identifying information about a client, (i.e., patient) receiving treatment or rehabilitation services for drug abuse, such a record is clearly a record maintained in connection with a drug abuse prevention function, and is subject to the provisions of this part. The fact that the record may also be required by statute or regulations pertaining to eligibility for Federal Financial Participation would in no way exempt the record from the prohibitions and requirements of this part. Thus, it would be unlawful and a violation of these regulations for such a record to be made available to a law enforcement agency, or to determine (without the prior written consent of the client) eligibility for other welfare benefits, or for any other administrative or investigative uses or purposes which would involve or result in an identification of the client to a third party.

§ 2.13 General rules regarding confidentiality.—Rules.

(a) *In general.* Records to which this part applies shall be confidential and may be disclosed only as authorized by this part, and may not otherwise be divulged in any civil, criminal, administrative, or legislative proceeding conducted by any Federal, State, or local authority, whether such proceeding is commenced before or after the effective date of this part.

(b) *Unconditional compliance required.* The prohibition upon unauthorized disclosure applies irrespective of whether the person seeking disclosure already has the information sought, has other means of obtaining it, enjoys official status, has obtained a subpoena, or asserts any other justification or basis for disclosure not expressly authorized under this part.

(c) *Information covered by prohibition.* The prohibition on unauthorized disclosure covers all information about patients, including, their attendance or absence, physical whereabouts, or status as patients, whether or not recorded, in the possession of program personnel, except as provided in paragraph (d) of this section.

(d) *Crimes on program premises or against program personnel.* Where a patient commits or threatens to commit a crime on the premises of the program or against personnel of the program, nothing in this part shall be construed as prohibiting personnel of the program from seeking the assistance of, or reporting such crime to, a law enforcement agency, but such report shall not identify the suspect as a patient. In any such situation, immediate consideration should be given to seeking an order under Subpart E of this part to permit the disclosure of such limited information about the patient as may be necessary under the circumstances.

(e) *Implicit and negative disclosures prohibited.* The disclosure that a person (whether actual or fictitious) answering to a particular description, name, or other identification is not or has not been attending a program, whether over a period of time or on a particular occasion, is fully as much subject to the prohibitions and conditions of this part as a disclosure that such a person is or has been attending such a program. Any improper or unauthorized request for any disclosure of records or information subject to this part must be met by a noncommittal response.

(f) *In-patients and residents.* The presence of any in-patient in a medical facility or resident in a residential facility for the treatment of drug or alcohol abuse may be acknowledged to callers and visitors with his written consent. Without such consent, the presence of any in-patient or resident in a facility for the treatment of a variety of conditions may be acknowledged it done in such a way as not to indicate that the patient is being treated for drug or alcohol abuse.

§ 2.13–1 General rules regarding confidentiality.—Basis and purpose.

(a) Section 2.13(a) enunciates the general principle of the statutory provisions, and is unchanged from § 1401.03 of the previous regulations.

(b) Sections 2.13(b) and 2.13(c) have been added on the basis of written comments on the draft regulations published August 22, 1974, in which there was a documented report that counsel for a program had advised the program that it could furnish information to the FBI about patients without their written consent and without completing a full judicial proceeding in accordance with Subpart E of this part. Sections 2.13(b) and 2.13(c) should clarify the original intent of the statutes and regulations to the extent of precluding such errors in the future.

(c) In the situation described in § 2.13(d), the desirability of the general prophylactic rule prohibiting disclosures by program personnel about patients regardless of whether such disclosures are from a written record must yield to the practical necessity to permit protection from, and prompt reporting of, criminal acts. In the preface to the first set of regulations issued under 21 U.S.C. 1175, it was emphasized that the operation of that section "in no way creates a sanctuary for criminals." (37 FR 24636, November 17, 1972). Section 2.13(d) is consistent with that contemporaneous administrative construction.

(d) Section 2.13(e) is adapted from § 1401.11 of the August 22, 1974 draft. The suggestion that this part be cited when declining to give information has been deleted on the basis of comments that correctly pointed out that such a citation, if given by an institution or program maintaining some records covered by this part and some not, would serve to identify the records inquired about as pertaining to treatment covered by this part.

Section 2.13(f) merely clarifies the effect of the preceding paragraphs in the special situations to which paragraph (f) relates.

§ 2.14 Penalty for Violations.—Rules.

(a) *Penalty provided by law.* Any person who violates any provision of the authorizing legislation or any provision of this part shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(b) *Application to subsequent offenses.* Where a defendant has committed one offense under either section authorizing this part or any provision of this part authorized by that section, any offense thereafter committed under the same section or any provision of this part authorized under that section shall be treated as a subsequent offense.

§ 2.14–1 Penalty for violations.—Basis and purpose.

(a) Section 2.14 states the criminal penalty provided for in subsection (f) of the sections authorizing this part. It is included in this part for convenience and completeness. Some of the comments received on this section when originally proposed suggested that criminal penalties for violation should include imprisonment, but such a change would have to be made by legislation rather than rulemaking.

(b) Section 2.14(b) clarifies the intention that the "subsequent offense" need not be identical to the first offense, as long as it is committed with respect to the same statutory section. For example, a person whose first offense had consisted of improperly releasing the name of a patient in an alcoholism treatment program would be punishable for a "subsequent offense" if he later gives out information from the diagnostic work-up of an alcoholism patient.

§ 2.15 Minor patients.—Rules.

(a) *Definition of minor.* The term "minor" means a person who has not attained the age of 18 years or, in a State where a different age is expressly provided by State law as the age at which a person ceases to be a minor, the age prescribed by the law of such State.

(b) *Consent to disclosure in general.* Except as provided in paragraph (c), where consent is required for any disclosure under this part, such consent in the case of a minor must be given by both the minor and his parent, guardian, or other person authorized under State law to act in his behalf, but any disclosure made after the patient has ceased to be a minor may be consented to only by the patient.

(c) *Rule when State law authorizes treatment without parental consent.* Whenever a patient, acting alone, has the

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 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 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 mould 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, mould 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 mere 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 mere 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 mere 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 beheld 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 law 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 been 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 affect 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 interpretive 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] (1074). 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 singed.

(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 §231(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 siren 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 rolemaking 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 126 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 current 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 probibition 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 any 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 mould 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 or 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 reasonable 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 referals.—Rules.

(a) *Consent authorized.* Where participation by an individual in 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 636 (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 lesgislation. 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 or 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 pertauning 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 discribed 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 bendificiaries 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.

(h) 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 he 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.

(1) 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 two 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) thereon 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 examinntion 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 examination.—Basis and purpose.

Confidence on the part of treatment program personnel in the integrity of auditing and regulators 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 explored 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 resistrant, 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 without 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 (e) 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 comfidentiality 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 last 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 consressional 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 Inaplicability 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, it 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 paragaph (b) of this section, the scope or 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 puposes 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 older 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 fall 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 progam 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.

(e) *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 these of an under cover 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 autharized 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.

[FR Doc. 75–17169 Filed 6–27–75; 9:38 am]

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.

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