

concurrence of the EPA with respect to those provisions of the proposed program amendment that relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). However, none of the revisions that Texas proposed to make in this amendment pertain to air or water quality standards. Therefore, OSM did not request EPA's concurrence.

Pursuant to 732.17(h)(11)(i), OSM solicited comment on the proposed amendment from EPA (Administrative Record No. TX-593.01). EPA did not respond to OSM's request.

State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Pursuant to 30 CFR 732.17(h)(4), OSM is required to solicit comments on proposed amendments which may have an effect on historic properties from the SHPO and ACHP. OSM solicited comments on the proposed amendment from the SHPO and ACHP (Administrative Record No. TX-593.01). Neither SHPO nor ACHP responded to OSM's request.

V. Director's Decision

Based on the above findings, the Director approves the proposed amendment as submitted by Texas on August 11, 1995, and as revised on September 25, 1995, concerning self-bonding alternative financial requirements for a business and governmental entities.

The Director approves the rules as proposed by Texas with the provision that they be fully promulgated in identical form to the rules submitted to and reviewed by OSM and the public.

The Federal regulations at 30 CFR 943, codifying decisions concerning the Texas program, are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to bring their programs into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

VI. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778

(Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

List of Subjects in 30 CFR Part 943

Intergovernmental relations, Surface mining, Underground mining.

Dated: February 1, 1995.

Brent Wahlquist,
Regional Director, Mid-Continent Regional Coordinating Center.

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 943—TEXAS

1. The authority citation for Part 943 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 943.15 is amended by adding paragraph (1) to read as follows:

§ 943.15 Approval of regulatory program amendments.

* * * * *

(1) The revisions to the following regulations at 16 Texas Administrative Code 11.221, the Coal Mining Regulations of the Railroad Commission of Texas, as submitted to OSM on August 11, 1995, and as revised on September 25, 1995, are approved effective December 13, 1995.

TCMR 806.309(j)(2)(C)(iv)
(I)(A), (B), and (C).

Self-bonding: financial requirements for a business and governmental entities, Alternative Financial Eligibility Criteria Test I.

TCMR 806.309(j)(2)(C)(iv)
(II)(A), (B), and (C).

Self-bonding: financial requirements for a business and governmental entities, Alternative Financial Eligibility Criteria Test II.

[FR Doc. 95-30330 Filed 12-12-95; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900-AE28

Confidentiality of Certain Medical Records

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document establishes Department of Veterans Affairs (VA) regulations to implement specific provisions of the Veterans Omnibus Health Care Act of 1976 and the Veterans' Benefits and Services Act of 1988 concerning the confidentiality of certain medical records. These regulations protect the confidentiality of VA records pertaining to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus (HIV), and sickle cell anemia.

EFFECTIVE DATE: January 12, 1996.

FOR FURTHER INFORMATION CONTACT: Celia Winter, Program Specialist, Veterans Health Administration (161F), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, (202) 273-6274.

SUPPLEMENTARY INFORMATION: On July 26, 1993, at 58 FR 39703, VA published a notice of proposed rulemaking (NPRM) concerning the confidentiality of VA records pertaining to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus (HIV) and sickle cell anemia treatment, rehabilitation, education, training, evaluation and research information. Interested parties were invited to submit written comments on or before August 25, 1993. Two comments were received.

Background

VA was mandated by the Veterans Omnibus Health Care Act of 1976 and the Veterans' Benefits and Services Act of 1988 to publish its own regulations relative to the confidentiality of medical records relating to drug abuse, alcoholism or alcohol abuse, infection with the HIV, and sickle cell anemia. VA, generally, has been following the Department of Health and Human Services' regulations on drug and alcohol abuse which were published in the Federal Register, July 1, 1975. The Department of Health and Human Services (HHS) regulations (42 CFR §§ 2.1-2.67) were promulgated with the enactment of legislation specific to alcohol and drug abuse programs and confidentiality of records. The regulations take into consideration the existing HHS regulations in implementing the confidentiality section of the Veterans Omnibus Health Care Act of 1976. Editorial and substantive changes were made to the HHS regulations which were published in the Federal Register, June 9, 1987.

The historical development of the regulations begins with Pub. L. 93-282, "Comprehensive Alcohol Abuse and

Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974," which provided that the then Administrator of Veterans Affairs, through the then Chief Medical Director, consistent with responsibilities under Title 38, United States Code, prescribe regulations applicable to the confidentiality of medical records maintained in connection with the provision of hospital care, nursing home care, domiciliary care and medical services under Title 38 to patients suffering from alcohol abuse, alcoholism, and drug abuse. In prescribing and implementing these regulations, the Secretary of Veterans Affairs was required to consult with the Secretary of HHS in order to achieve the maximum possible coordination of the regulations.

Congress, recognizing that the particular problems of confidentiality of records in the VA health care system would best be handled by placing applicable provisions in Title 38, United States Code, added a new § 4132, now § 7332, to Title 38, United States Code, with the enactment of Pub. L. 94-581, Veterans Omnibus Health Care Act of 1976. The intent of this legislation was to ensure confidentiality of certain medical records by establishing sanctions for unauthorized disclosure of information, while at the same time, meeting the legitimate needs for disclosure under certain conditions. As part of this legislation, Congress imposed upon VA requirements similar to those of Pub. L. 93-282 noted above (38 U.S.C. § 7334, formerly § 4134).

Section 111 of Pub. L. 94-581 replaced, for VA purposes, the provisions of Sections 122(a) and 303 of Pub. L. 93-282 (21 U.S.C. § 1175, for drug records; 42 U.S.C. § 4582, for alcohol records) as the statutory base for confidentiality of drug and alcohol abuse records for those patients treated by VA medical facilities. Additionally, it replaced Section 109 of Pub. L. 93-82 (38 U.S.C. § 1753(b), formerly § 653(b)) which provided for confidentiality of sickle cell anemia records and required VA to promulgate regulations. Pub. L. 94-581, Veterans Omnibus Health Care Act of 1976, addressed all three subjects—drug abuse, alcoholism and sickle cell anemia records—in its confidentiality mandate. Section 121 of Pub. L. 100-322 provided for the confidentiality of records relating to infection with the HIV. Accordingly, drug and alcohol abuse, infection with the HIV, and sickle cell anemia records are included in these regulations.

VA has followed regulations on the confidentiality of patients' records

related to drug and alcohol abuse as prescribed in 1975 by the Secretary of HHS. Certain provisions of the HHS regulations are inconsistent with VA requirements and these new VA regulations address those inconsistencies. Staff at HHS reviewed a draft of the regulations prior to publication and changes were made based on the comments where there was statutory authority for the change.

The HHS regulations as revised in 1987 and further amended on May 5, 1995, cover only alcohol and drug abuse information that is obtained by a specialized program or specific provider whose primary function is the provision of alcohol or drug abuse diagnosis, treatment, or referral for treatment. The 1987 regulations do not cover alcohol and drug abuse information obtained by health care facilities which provide alcohol and drug abuse care only as an incident to the provision of general medical care. The VA regulations include *all* records which are maintained in connection with the performance of any VA program or activity (including education, training, evaluation, treatment, rehabilitation or research) relating to drug abuse, alcoholism, infection with the HIV, or sickle cell anemia in order to provide greater confidentiality for patients who are provided care for these conditions. On May 5, 1995, HHS published a final rule in 60 FR 22296, amending its confidentiality regulations with regard to the definition of "program." HHS's final rule was in direct response to the holding made by the Ninth Circuit in a case involving the VA, *United States v. Eide*, 875 F.2d 1429, 1438 (9th Cir. 1989). There the court held the VAMC's (VA medical center) general emergency room to be a "program" as defined by the HHS regulations, upon which VA's policy is based. In its final rule, HHS limited the definition of "program" to: (1) an individual or entity, or an identified unit within a medical care facility, who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment, or (2) medical personnel or other staff in a general medical care facility, whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers. VA's final regulations DO NOT reflect the same regulatory language concerning the definition of a "program" as the HHS regulations due to the VA's treatment of the encompassed conditions as an integral part of the VA medical health care system and not a separate program

isolated from other Department functions. VA believes, as does HHS, that clarification of this point is necessary to help prevent other courts from ruling as the Ninth Circuit did in *Eide*, even as to the VA version of these regulations. Therefore, a specific example has been added to § 1.460(k)(2) to reflect that one-time emergency room care, where neither treatment or referral for treatment of the underlying drug or alcohol abuse condition is offered or sought, does not fall within the purview of these regulations. It was determined that a specific example was necessary to distinguish between those instances where an individual is brought into an emergency room for a potential drug overdose, receives one-time treatment and is released, from those instances where an individual enters an emergency room with, or acquires while there, the purpose of seeking treatment for his or her drug addiction, or VA offers treatment for such condition.

Discussion of Comments

A total of two comments were received—one from a national medical specialty society and the other from a not-for-profit public interest law firm that specializes in legal and policy issues related to substance abuse and HIV/AIDS. One of the commenters suggested that the regulations be revised to include a requirement that patients be given written notice and summary of the confidentiality protections of the subject records by §§ 1.460 through 1.499. This provision is included in the HHS regulations at 42 CFR 2.22. The HHS regulations provide confidentiality protections for drug or alcohol abuse information that is obtained by a specialized program or specific provider whose primary function is the provision of alcohol or drug abuse diagnosis, treatment, or referral for treatment. Consequently, the patients are easily identified at the initiation of treatment and can be provided the written notice and summary. The VA regulations, however, provide for the confidentiality of all records which are maintained in connection with the performance of any VA program or activity. Consequently, medical care may be given for drug or alcohol abuse, sickle cell anemia, or infection with the HIV in conjunction with, and after the initiation of medical care for other conditions. These patients are not as readily recognized as an individual who should be provided with the written notice and summary of the confidentiality protections. While VA will take efforts to notify patients of these provisions through notices in patient information handouts, handbooks, etc., it would not be

possible to positively assure every patient will receive the notification as would be required if provided for in the regulations. Thus, we have not adopted this suggestion.

The same commenter suggested the addition of a provision that would provide for limitations on court-ordered disclosure of confidential communications. They suggested that disclosure of confidential communications that a patient provides to a treatment service be limited to those situations where a serious crime is reported or threatened, or where the patient has already testified about confidential communications in a formal proceeding, such as is provided for by HHS at 42 CFR 2.63. The final regulations have been revised to include the suggested provision. This is consistent with 38 U.S.C. 7334 which requires that the VA regulations follow the HHS regulations as far as possible. Accordingly, it has been added at § 1.491. The provisions previously published at § 1.491 and following have been renumbered following the newly inserted provision.

Another commenter addressed § 1.489(c) which provides for the release of identifiable patient records to "congressional committees or subcommittees for program oversight and evaluation if such records pertain to any matter within the jurisdiction of such committee or subcommittee." The commenter did not understand the necessity for a broad based authorization for the release of individually identifiable patient records for program oversight and evaluation and assumed that Congressional committees would not have a need for individual records, but rather a compilation of information without patient identifiers. It was further stated that the standards of disclosure to Congress of individually identifiable patient records for these diagnoses should be the same as for other Federal and State entities. We do not agree with this suggestion. As part of their oversight responsibilities, Congressional committees do review individual patient treatment issues as well as overall program issues. In order to carry out this function, they need access to treatment information concerning directly affected individuals. These responsibilities are not shared nor are they the responsibility of other Federal and State entities. For these reasons, the provision was not revised.

The same commenter recommended a revision of section 1.487 which provides for the notification of information related to infection with the human immunodeficiency virus to the spouse

or sexual partner of a patient. Disclosure may be made only after the patient's physician or counselor, after making reasonable efforts to counsel and encourage the patient to provide the information to the spouse or sexual partner, reasonably believes that the patient will not provide the information and that the disclosure is necessary to protect the health of the spouse or sexual partner. The commenter recommended that the provision be refined to include a focus on risk behavior modification. No changes were made based on the comment. The regulation addresses the issue of confidentiality and the disclosure, under certain conditions, of the information to individuals who are at risk. The issue of risk behavior modification is best addressed in treatment and therapeutic publications, policies, guidelines, etc.

These regulations 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.

An additional, clarifying change to the regulations has been made concerning internal non-patient investigations and healthcare inspections conducted by the Office of Inspector General (OIG). During the internal review process, a question was raised by the VA's OIG as to whether OIG would be prohibited access to records protected by the regulations in cases involving healthcare inspections or criminal investigations of non-patients. Because the statute prohibits access to such records only where the patient is the subject of an investigation, and because the OIG would have a need for the information in connection with their duties, we have included language in § 1.461(c) that explicitly extends the exception of coverage of the regulations to healthcare inspections and non-patient investigations conducted by OIG. We have also added language clarifying that confidential information obtained by VA components, including OIG, who have a need for the information in connection with their duties, may not be redisclosed except in accordance with the regulations. These clarifications from the proposed rule merely reflect our interpretation of statutory authority.

Other nonsubstantive changes have been added for purposes of clarity.

Executive Order 12866

This regulatory action has been reviewed by the Office of Management and Budget under Executive Order 12866.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 600–612. This rule will affect VA beneficiaries and will not affect small businesses. Therefore, pursuant to 5 U.S.C. 605(b), this final rule is exempt from the initial and final regulatory flexibility analyses requirements of §§ 603 and 604.

The Paperwork Reduction Act

Section 1.475 of this regulation contains an information collection requirement that has been approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act and has been assigned OMB Control No. 2900–0544 (expiration date is October 31, 1996). The Department of Veterans Affairs estimates that it will take an average of five minutes per respondent to provide the required information for the consent form and there will be approximately 20,640 such requests made per year.

List of Subjects in 38 CFR Part 1

Administrative procedures, Privacy Act, Recordkeeping.

Approved: August 24, 1995.

Jesse Brown,

Secretary of Veterans Affairs.

In consideration of the foregoing, the Department of Veterans Affairs amends 38 CFR part 1, General Provisions, as follows:

PART 1—GENERAL

1. The authority citation for part 1 is revised to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

2. Sections 1.460 through 1.499, an undesignated center heading, note, and authority citation preceding § 1.460, and undesignated center headings preceding §§ 1.475, 1.475 and 1.485 and 1.490 are added to read as follows:

Release of Information from Department of Veterans Affairs (VA) Records Relating to Drug Abuse, Alcoholism or Alcohol Abuse, Infection with the Human Immunodeficiency Virus (HIV), or Sickle Cell Anemia

Sec.

1.460 Definitions.

1.461 Applicability.

1.462 Confidentiality restrictions.

1.463 Criminal penalty for violations.

1.464 Minor patients.

1.465 Incompetent and deceased patients.

1.466 Security for records.

1.467 Restrictions on the use of identification cards and public signs.

1.468 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.

1.469 Patient access and restrictions on use.

1.470–1.474 [Reserved]

Disclosures With Patient's Consent

1.475 Form of written consent.

1.476 Prohibition on redisclosure.

1.477 Disclosures permitted with written consent.

1.478 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs; not applicable to records relating to sickle cell anemia or infection with the human immunodeficiency virus.

1.479 Disclosures to elements of the criminal justice system which have referred patients.

1.480–1.484 [Reserved]

Disclosures Without Patient Consent

1.485 Medical emergencies.

1.486 Disclosure of information related to infection with the human immunodeficiency virus to public health authorities.

1.487 Disclosure of information related to infection with the human immunodeficiency virus to the spouse or sexual partner of the patient.

1.488 Research activities.

1.489 Audit and evaluation activities.

Court Orders Authorizing Disclosures and Use

1.490 Legal effect of order.

1.491 Confidential communications.

1.492 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.

1.493 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.

1.494 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.

1.495 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute VA or employees of VA.

1.496 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of VA.

1.497–1.499 [Reserved]

Release of Information From Department of Veterans Affairs Records Relating to Drug Abuse, Alcoholism or Alcohol Abuse, Infection With the Human Immunodeficiency Virus (HIV), or Sickle Cell Anemia

Note: Sections 1.460 through 1.499 of this part concern the confidentiality of information relating to drug abuse,

alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia in VA records and are applicable in combination with other regulations pertaining to the release of information from VA records. Sections 1.500 through 1.527, Title 38, Code of Federal Regulations, implement the provisions of 38 U.S.C. §§ 5701 and 5702. Sections 1.550 through 1.559 implement the provisions of 5 U.S.C. § 552 (The Freedom of Information Act). Sections 1.575 through 1.584 implement the provisions of 5 U.S.C. § 552a (The Privacy Act of 1974).

The provisions of §§ 1.460 through 1.499 of this part pertain to any program or activity, including education, treatment, rehabilitation or research, which relates to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia. The statutory authority for the drug abuse provisions and alcoholism or alcohol abuse provisions of §§ 1.460 through 1.499 is Sec. 111 of Pub. L. 94–581, the Veterans Omnibus Health Care Act of 1976 (38 U.S.C. §§ 7331 through 7334), the authority for the human immunodeficiency virus provisions is Sec. 121 of Pub. L. 100–322, the Veterans' Benefits and Services Act of 1988 (38 U.S.C. § 7332); the authority for the sickle cell anemia provisions is Sec. 109 of Pub. L. 93–82, the Veterans Health Care Expansion Act of 1973 (38 U.S.C. §§ 1751–1754).

Authority: 38 USC 1751–1754 and 7331–7334.

§ 1.460 Definitions.

For purposes of §§ 1.460 through 1.499 of this part, the following definitions apply:

Alcohol abuse. The term “alcohol abuse” means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

Contractor. The term “contractor” means a person who provides services to VA such as data processing, dosage preparation, laboratory analyses or medical or other professional services. Each contractor shall be required to enter into a written agreement subjecting such contractor to the provisions of §§ 1.460 through 1.499 of this part; 38 U.S.C. 5701 and 7332; and 5 U.S.C. 552a and 38 CFR 1.576(g).

Diagnosis. The term “diagnosis” means any reference to an individual's alcohol or drug abuse or to a condition which is identified as having been caused by that abuse or any reference to sickle cell anemia or infection with the human immunodeficiency virus which is made for the purpose of treatment or

referral for treatment. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by §§ 1.460 through 1.499 of this part. These regulations do not apply to a diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved is not an alcohol or drug abuser (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).

Disclose or disclosure. The term "disclose" or "disclosure" means a communication of patient identifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

Drug abuse. The term "drug abuse" means the use of a psychoactive substance for other than medicinal purposes which impairs the physical, mental, emotional, or social well-being of the user.

Infection with the human immunodeficiency virus (HIV). The term "infection with the human immunodeficiency virus (HIV)" means the presence of laboratory evidence for human immunodeficiency virus infection. For the purposes of §§ 1.460 through 1.499 of this part, the term includes the testing of an individual for the presence of the virus or antibodies to the virus and information related to such testing (including tests with negative results).

Informant. The term "informant" means an individual who is a patient or employee or who becomes a patient or employee at the request of a law enforcement agency or official and who at the request of a law enforcement agency or official observes one or more patients or employees for the purpose of reporting the information obtained to the law enforcement agency or official.

Patient. The term "patient" means any individual or subject who has applied for or been given a diagnosis or treatment for drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia and includes any individual who, after arrest on a criminal charge, is interviewed and/or tested in connection with drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia in order to determine that individual's eligibility to participate in a treatment or rehabilitation program. The term patient includes an individual who has been diagnosed or treated for alcoholism, drug abuse, HIV infection, or sickle cell

anemia for purposes of participation in a VA program or activity relating to those four conditions, including a program or activity consisting of treatment, rehabilitation, education, training, evaluation, or research. The term "patient" for the purpose of infection with the human immunodeficiency virus or sickle cell anemia, includes one tested for the disease.

Patient identifying information. The term "patient identifying information" means the name, address, social security number, fingerprints, photograph, 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 number assigned to a patient by a treatment program, if that number does not consist of, or contain numbers (such as social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the treatment program.

Person. The term "person" means an individual, partnership, corporation, Federal, State or local government agency, or any other legal entity.

Records. The term "records" means any information received, obtained or maintained, whether recorded or not, by an employee or contractor of VA, for the purpose of seeking or performing VA program or activity functions relating to drug abuse, alcoholism, tests for or infection with the human immunodeficiency virus, or sickle cell anemia regarding an identifiable patient. A program or activity function relating to drug abuse, alcoholism, infection with the human immunodeficiency virus, or sickle cell anemia includes evaluation, treatment, education, training, rehabilitation, research, or referral for one of these conditions. Sections 1.460 through 1.499 of this part apply to a primary or other diagnosis, or other information which identifies, or could reasonably be expected to identify, a patient as having a drug or alcohol abuse condition, infection with the human immunodeficiency virus, or sickle cell anemia (e.g., alcoholic psychosis, drug dependence), but only if such diagnosis or information is received, obtained or maintained for the purpose of seeking or performing one of the above program or activity functions. Sections 1.460 through 1.499 of this part do not apply if such diagnosis or other information is not received, obtained or maintained for the purpose of seeking or performing a function or activity relating to drug abuse, alcoholism,

infection with the human immunodeficiency virus, or sickle cell anemia for the patient in question. Whenever such diagnosis or other information, not originally received or obtained for the purpose of obtaining or providing one of the above program or activity functions, is subsequently used in connection with such program or activity functions, those original entries become a "record" and §§ 1.460 through 1.499 of this part thereafter apply to those entries. Segregability: these regulations do not apply to records or information contained therein, the disclosure of which (the circumstances surrounding the disclosure having been considered) could not reasonably be expected to disclose the fact that a patient has been connected with a VA program or activity function relating to drug abuse, alcoholism, infection with the human immunodeficiency virus, or sickle cell anemia.

(1) The following are examples of instances whereby records or information related to alcoholism or drug abuse are covered by the provisions of §§ 1.460 through 1.499 of this part:

(i) A patient with alcoholic delirium tremens is admitted for detoxification. The patient is offered treatment in a VA alcohol rehabilitation program which he declines.

(ii) A patient who is diagnosed as a drug abuser applies for and is provided VA drug rehabilitation treatment.

(iii) While undergoing treatment for an unrelated medical condition, a patient discusses with the physician his use and abuse of alcohol. The physician offers VA alcohol rehabilitation treatment which is declined by the patient.

(2) The following are examples of instances whereby records or information related to alcoholism or drug abuse are not covered by the provisions of §§ 1.460 through 1.499 of this part:

(i) A patient with alcoholic delirium tremens is admitted for detoxification, treated and released with no counseling or treatment for the underlying condition of alcoholism.

(ii) While undergoing treatment for an unrelated medical condition, a patient informs the physician of a history of drug abuse fifteen years earlier with no ingestion of drugs since. The history and diagnosis of drug abuse is documented in the hospital summary and no treatment is sought by the patient or offered or provided by VA during the current period of treatment.

(iii) While undergoing treatment for injuries sustained in an accident, a patient's medical record is documented

to support the judgment of the physician to prescribe certain alternate medications in order to avoid possible drug interactions in view of the patient's enrollment and treatment in a non-VA methadone maintenance program. The patient states that continued treatment and follow-up will be obtained from private physicians and VA treatment for the drug abuse is not sought by the patient nor provided or offered by the staff.

(iv) A patient is admitted to the emergency room suffering from a possible drug overdose. The patient is treated and released; a history and diagnosis of drug abuse may be documented in the hospital summary. The patient is not offered treatment for the underlying conditions of drug abuse, nor is treatment sought by the patient for that condition.

Third party payer. The term "third party payer" means a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his or her family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

Treatment. The term "treatment" means the management and care of a patient for drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia, or a condition which is identified as having been caused by one or more of these conditions, in order to reduce or eliminate the adverse effects upon the patient. The term includes testing for the human immunodeficiency virus or sickle cell anemia.

Undercover agent. The term "undercover agent" means an officer of any Federal, State, or local law enforcement agency who becomes a patient or employee for the purpose of investigating a suspected violation of law or who pursues that purpose after becoming a patient or becoming employed for other purposes.

(Authority: 38 U.S.C. 7334)

§ 1.461 Applicability.

(a) General.

(1) **Restrictions on disclosure.** The restrictions on disclosure in these regulations apply to any information whether or not recorded, which:

(i) Would identify a patient as an alcohol or drug abuser, an individual tested for or infected with the human immunodeficiency virus (HIV), hereafter referred to as HIV, or an individual with sickle cell anemia, either directly, by reference to other publicly available information, or through verification of

such an identification by another person; and

(ii) Is provided or obtained for the purpose of treating alcohol or drug abuse, infection with the HIV, or sickle cell anemia, making a diagnosis for that treatment, or making a referral for that treatment as well as for education, training, evaluation, rehabilitation and research program or activity purposes.

(2) **Restriction on use.** The restriction on use of information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any information, whether or not recorded, which is maintained for the purpose of treating drug abuse, alcoholism or alcohol abuse, infection with the HIV, or sickle cell anemia, making a diagnosis for that treatment, or making a referral for that treatment as well as for education, training, evaluation, rehabilitation, and research program or activity purposes.

(b) **Period covered as affecting applicability.** The provisions of §§ 1.460 through 1.499 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 alcoholism or alcohol abuse; or before September 1, 1973, in the case of testing, diagnosis or treatment of sickle cell anemia; or before May 20, 1988, in the case of testing, diagnosis or treatment for an infection with the HIV.

(c) Exceptions.

(1) **Department of Veterans Affairs and Armed Forces.** The restrictions on disclosure in §§ 1.460 through 1.499 of this part do not apply to communications of information between or among those components of VA who have a need for the information in connection with their duties in the provision of health care, adjudication of benefits, or in carrying out administrative responsibilities related to those functions, including personnel of the Office of the Inspector General who are conducting audits, evaluations, healthcare inspections, or non-patient investigations, or between such components and the Armed Forces, of information pertaining to a person relating to a period when such person is or was subject to the Uniform Code of Military Justice. Information obtained by VA components under these circumstances may be disclosed outside of VA to prosecute or investigate a non-patient only in accordance with § 1.495

of this part. Similarly, the restrictions on disclosure in §§ 1.460 through 1.499 of this part do not apply to communications of information to the Department of Justice or U.S. Attorneys who are providing support in civil litigation or possible litigation involving VA.

(2) **Contractor.** The restrictions on disclosure in §§ 1.460 through 1.499 of this part do not apply to communications between VA and a contractor of information needed by the contractor to provide his or her services.

(3) **Crimes on VA premises or against VA personnel.** The restrictions on disclosure and use in §§ 1.460 through 1.499 of this part do not apply to communications from VA personnel to law enforcement officers which:

(i) Are directly related to a patient's commission of a crime on the premises of the facility or against personnel of VA or to a threat to commit such a crime; and

(ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address to the extent authorized by 38 U.S.C. 5701(f)(2), and that individual's last known whereabouts.

(4) Undercover agents and informants.

(i) Except as specifically authorized by a court order granted under § 1.495 of this part, VA may not knowingly employ, or admit as a patient, any undercover agent or informant in any VA drug abuse, alcoholism or alcohol abuse, HIV infection, or sickle cell anemia treatment program.

(ii) No information obtained by an undercover agent or informant, whether or not that undercover agent or informant is placed in a VA drug abuse, alcoholism or alcohol abuse, HIV infection, or sickle cell anemia treatment program pursuant to an authorizing court order, may be used to criminally investigate or prosecute any patient unless authorized pursuant to the provisions of § 1.494 of this part.

(iii) The enrollment of an undercover agent or informant in a treatment unit shall not be deemed a violation of this section if the enrollment is solely for the purpose of enabling the individual to obtain treatment for drug or alcohol abuse, HIV infection, or sickle cell anemia.

(d) Applicability to recipients of information.

(1) **Restriction on use of information.** In the absence of a proper § 1.494 court order, the restriction on the use of any information subject to §§ 1.460 through 1.499 of this part to initiate or

substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any person who obtains that information from VA, regardless of the status of the person obtaining the information or of whether the information was obtained in accordance with §§ 1.460 through 1.499 of this part. This restriction on use bars, among other things, the introduction of that information as evidence in a criminal proceeding and any other use of the information to investigate or prosecute a patient with respect to a suspected crime. Information obtained by undercover agents or informants (see paragraph (c) of this section) or through patient access (see § 1.469 of this part) is subject to the restriction on use.

(2) *Restrictions on disclosures—third-party payers and others.* The restrictions on disclosure in §§ 1.460 through 1.499 of this part apply to third-party payers and persons who, pursuant to a consent, receive patient records directly from VA and who are notified of the restrictions on redisclosure of the records in accordance with § 1.476 of this part.

(Authority: 38 U.S.C. 7332(e) and 7334)

§ 1.462 Confidentiality restrictions.

(a) *General.* The patient records to which §§ 1.460 through 1.499 of this part apply may be disclosed or used only as permitted by these regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority. Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

(b) *Unconditional compliance required.* The restrictions on disclosure and use in §§ 1.460 through 1.499 of this part apply whether the person seeking the information already has it, has other means of obtaining it, is a law enforcement or other official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by §§ 1.460 through 1.499 of this part. These provisions do not prohibit VA from acting accordingly when there is no disclosure of information.

(c) *Acknowledging the presence of patients: responding to requests.*

(1) The presence of an identified patient in a VA facility for the treatment or other VA program activity relating to drug abuse, alcoholism or alcohol abuse, infection with the HIV, or sickle cell anemia may be acknowledged only if the patient's written consent is obtained in accordance with § 1.475 of this part

or if an authorizing court order is entered in accordance with §§ 1.490 through 1.499 of this part. Acknowledgment of the presence of an identified patient in a facility is permitted if the acknowledgment does not reveal that the patient is being treated for or is otherwise involved in a VA program or activity concerning drug abuse, alcoholism or alcohol abuse, infection with the HIV, or sickle cell anemia.

(2) Any answer to a request for a disclosure of patient records which is not permissible under §§ 1.460 through 1.499 of this part must be made in a way that will not affirmatively reveal that an identified individual has been, or is being diagnosed or treated for drug abuse, alcoholism or alcohol abuse, infection with the HIV, or sickle cell anemia. These regulations do not restrict a disclosure that an identified individual is not and never has been a patient.

(Authority: 38 U.S.C. 7334)

§ 1.463 Criminal penalty for violations.

Under 38 U.S.C. 7332(g), any person who violates any provision of this statute or §§ 1.460 through 1.499 of this part shall be fined not more than \$5,000 in the case of a first offense, and not more than \$20,000 for a subsequent offense.

(Authority: 38 U.S.C. 7332(g))

§ 1.464 Minor patients.

(a) *Definition of minor.* As used in §§ 1.460 through 1.499 of this part the term "minor" means a person who has not attained the age of majority specified in the applicable State law, or if no age of majority is specified in the applicable State law, the age of eighteen years.

(b) *State law not requiring parental consent to treatment.* If a minor patient acting alone has the legal capacity under the applicable State law to apply for and obtain treatment for drug abuse, alcoholism or alcohol abuse, infection with the HIV, or sickle cell anemia, any written consent for disclosure authorized under § 1.475 of this part may be given only by the minor patient. This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement. Sections 1.460 through 1.499 of this part do not prohibit a VA facility from refusing to provide nonemergent treatment to an otherwise ineligible minor patient until the minor patient consents to the disclosure

necessary to obtain reimbursement for services from a third party payer.

(c) *State law requiring parental consent to treatment.*

(1) Where State law requires consent of a parent, guardian, or other person for a minor to obtain treatment for drug abuse, alcoholism or alcohol abuse, infection with the HIV, or sickle cell anemia, any written consent for disclosure authorized under § 1.475 of this part must be given by both the minor and his or her parent, guardian, or other person authorized under State law to act in the minor's behalf.

(2) Where State law requires parental consent to treatment, the fact of a minor's application for treatment may be communicated to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf only if:

(i) The minor has given written consent to the disclosure in accordance with § 1.475 of this part; or

(ii) The minor lacks the capacity to make a rational choice regarding such consent as judged by the appropriate VA facility director under paragraph (d) of this section.

(d) *Minor applicant for service lacks capacity for rational choice.* Facts relevant to reducing a threat to the life or physical well being of the applicant or any other individual may be disclosed to the parent, guardian, or other person authorized under State law to act in the minor's behalf if the appropriate VA facility director judges that:

(1) A minor applicant for services lacks capacity because of extreme youth or mental or physical condition to make a rational decision on whether to consent to a disclosure under § 1.475 of this part to his or her parent, guardian, or other person authorized under State law to act in the minor's behalf, and

(2) The applicant's situation poses a substantial threat to the life or physical well-being of the applicant or any other individual which may be reduced by communicating relevant facts to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf.

(Authority: 38 U.S.C. 7334)

§ 1.465 Incompetent and deceased patients.

(a) *Incompetent patients other than minors.* 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, any consent which is required under §§ 1.460 through 1.499 of this part may be given by a court appointed legal guardian.

(b) *Deceased patients.*

(1) *Vital statistics.* Sec. 1.460 through 1.499 of this part do not restrict the disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.

(2) *Consent by personal representative.* Any other disclosure of information identifying a deceased patient as being treated for drug abuse, alcoholism or alcohol abuse, infection with the HIV, or sickle cell anemia is subject to §§ 1.460 through 1.499 of this part. If a written consent to the disclosure is required, the Under Secretary for Health or designee may, upon the prior written request of the next of kin, executor/executrix, administrator/administratrix, or other personal representative of such deceased patient, disclose the contents of such records, only if the Under Secretary for Health or designee determines such disclosure is necessary to obtain survivorship benefits for the deceased patient's survivor. This would include not only VA benefits, but also payments by the Social Security Administration, Worker's Compensation Boards or Commissions, or other Federal, State, or local government agencies, or nongovernment entities, such as life insurance companies.

(3) *Information related to sickle cell anemia.* Information related to sickle cell anemia may be released to a blood relative of a deceased veteran for medical follow-up or family planning purposes.

(Authority: 38 U.S.C. 7332(b)(3))

§ 1.466 Security for records.

(a) Written records which are subject to §§ 1.460 through 1.499 of this part must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use. Access to information stored in computers will be limited to authorized VA employees who have a need for the information in performing their duties. These security precautions shall be consistent with the Privacy Act of 1974 (5 U.S.C. 552a).

(b) Each VA facility shall adopt in writing procedures related to the access to and use of records which are subject to §§ 1.460 through 1.499 of this part.

(Authority: 38 U.S.C. 7334)

§ 1.467 Restrictions on the use of identification cards and public signs.

(a) No facility may require any patient to carry on their person while away from the facility premises any card or other object which would identify the patient as a participant in any VA drug

abuse, alcoholism or alcohol abuse, HIV infection, or sickle cell anemia treatment program. A facility may require patients to use or carry cards or other identification objects on the premises of a facility. Patients may not be required to wear clothing or colored identification bracelets or display objects openly to all facility staff or others which would identify them as being treated for drug or alcohol abuse, HIV infection, or sickle cell anemia.

(b) Treatment locations should not be identified by signs that would identify individuals entering or exiting these locations as patients enrolled in a drug or alcohol abuse, HIV infection, or sickle cell anemia program or activity.

(Authority: 38 U.S.C. 7334)

§ 1.468 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.

(a) *Research privilege description.* There may be concurrent coverage of patient identifying information by the provisions of §§ 1.460 through 1.499 of this part and by administrative action taken under Sec. 303(a) of the Public Health Service Act (42 U.S.C. 241(d) and the implementing regulations at 42 CFR Part 2a); or Sec. 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These "research privilege" statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) *Effect of concurrent coverage.* Sections 1.460 through 1.499 of this part restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under §§ 1.490 through 1.499 of this part of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes.

However, the research privilege granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any information which is permitted to be disclosed under those regulations. Thus,

if a court order entered in accordance with §§ 1.490 through 1.499 of this part authorizes a VA facility to disclose certain information about its patients, the facility may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

(Authority: 38 U.S.C. 7334)

§ 1.469 Patient access and restrictions on use.

(a) *Patient access not prohibited.* Sections 1.460 through 1.499 of this part do not prohibit a facility from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that VA maintains about the patient, subject to the provisions of the Privacy Act (5 U.S.C. 552a(d)(1)) and 38 CFR 1.577. If the patient is accompanied, giving access to the patient and the accompanying person will require a written consent by the patient which is provided in accordance with § 1.475 of this part.

(b) *Restrictions on use of information.* Information obtained by patient access to patient record is subject to the restriction on use of this information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 1.461(d)(1) of this part.

(Authority: 38 U.S.C. 7334)

§§ 1.470–1.474 [Reserved]**Disclosures With Patient's Consent****§ 1.475 Form of written consent.**

(a) Required elements. A written consent to a disclosure under §§ 1.460 through 1.499 of this part must include:

(1) The name of the facility permitted to make the disclosure (such a designation does not preclude the release of records from other VA health care facilities unless a restriction is stated on the consent).

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

(3) The name of the patient.

(4) The purpose of the disclosure.

(5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 1.464 of this part; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 1.465 of this part in lieu of the patient.

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

(8) A statement that the consent is subject to revocation at any time except to the extent that the facility which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

- (1) Has expired;
- (2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;
- (3) Is known to have been revoked; or
- (4) Is known, or through a reasonable effort could be known, by responsible personnel of VA to be materially false.

(c) *Notification of deficient consent.* Other than the patient, no person or entity may be advised that a special consent is required in order to disclose information relating to an individual participating in a drug abuse, alcoholism or alcohol abuse, HIV, or sickle cell anemia program or activity. Where a person or entity presents VA with an insufficient written consent for information protected by 38 U.S.C. 7332, VA must, in the process of obtaining a legally sufficient consent, correspond only with the patient whose records are involved, or the legal guardian of an incompetent patient or next of kin of a deceased patient, and not with any other person.

(d) It is not necessary to use any particular form to establish a consent referred to in paragraph (a) of this section, however, VA Form 10-5345, titled Request for and Consent to Release of Medical Records Protected by 38 U.S.C. 7332, may be used for such purpose.

(Authority: 38 U.S.C. 7332(a)(2) and (b)(1))

§ 1.476 Prohibition on redisclosure.

Each disclosure under §§ 1.460 through 1.499 of this part made with the patient's written consent must be accompanied by a written statement similar to the following:

This information has been disclosed to you from records protected by Federal confidentiality rules (38 CFR Part 1). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 38 CFR

Part 1. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient or patient with sickle cell anemia or HIV infection.

(Authority: 38 U.S.C. 7334)

§ 1.477 Disclosures permitted with written consent.

If a patient consents to a disclosure of his or her records under § 1.475 of this part, a facility may disclose those records in accordance with that consent to any individual or organization named in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 1.478 and 1.479 of this part, respectively.

(Authority: 38 U.S.C. 7332(b)(1))

§ 1.478 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs; not applicable to records relating to sickle cell anemia or infection with the HIV.

(a) Definitions.

For purposes of this section:

(1) *Central registry* means an organization which obtains from two or more member programs patient identifying information about individuals applying for maintenance treatment or detoxification treatment for the purpose of avoiding an individual's concurrent enrollment in more than one program.

(2) *Detoxification treatment* means the dispensing of a narcotic drug in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to withdrawal from the sustained use of a narcotic drug.

(3) *Maintenance treatment* means the dispensing of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

(4) *Member program* means a non-VA detoxification treatment or maintenance treatment program which reports patient identifying information to a central registry and which is in the same State as that central registry or is not more than 125 miles from any border of the State in which the central registry is located.

(b) *Restrictions on disclosure.* VA may disclose patient records to a central registry which is located in the same State or is not more than 125 miles from any border of the State or to any non-VA detoxification or maintenance treatment program not more than 200 miles away for the purpose of preventing the multiple enrollment of a patient only if:

(1) The disclosure is made when:

- (i) The patient is accepted for treatment;
- (ii) The type or dosage of the drug is changed; or
- (iii) The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

- (i) Patient identifying information;
- (ii) Type and dosage of the drug; and
- (iii) Relevant dates.

(3) The disclosure is made with the patient's written consent meeting the requirements of § 1.475 of this part, except that:

- (i) The consent must list the name and address of each central registry and each known non-VA detoxification or maintenance treatment program to which a disclosure will be made; and
- (ii) The consent may authorize a disclosure to any non-VA detoxification or maintenance treatment program established within 200 miles after the consent is given without naming any such program.

(c) *Use of information limited to prevention of multiple enrollments.* A central registry and any non-VA detoxification or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not redisclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a court order under §§ 1.490 through 1.499 of this part.

(Authority: 38 U.S.C. 7334)

§ 1.479 Disclosures to elements of the criminal justice system which have referred patients.

(a) VA may disclose information about a patient from records covered by §§ 1.460 through 1.499 of this part to those persons within the criminal justice system which have made participation in a VA treatment program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

(1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or posttrial release, probation or parole officers responsible for supervision of the patient); and

(2) The patient has signed a written consent as a condition of admission to the treatment program meeting the requirements of § 1.475 of this part (except paragraph (a)(8) which is

inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this section.

(b) *Duration of consent.* The written consent must state the period during which it remains in effect. This period must be reasonable, taking into account:

(1) The anticipated length of the treatment recognizing that revocation of consent may not generally be effected while treatment is ongoing;

(2) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when the final disposition will occur; and

(3) Such other factors as the facility, the patient, and the person(s) who will receive the disclosure consider pertinent.

(c) *Revocation of consent.* The written consent must state that it is revocable upon the passage of a specified amount of time or the occurrence of a specified, ascertainable event. The time or occurrence upon which consent becomes revocable may be no earlier than the individual's completion of the treatment program and no later than the final disposition of the conditional release or other action in connection with which consent was given.

(d) *Restrictions on redisclosure and use.* A person who receives patient information under this section may redisclose and use it only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the consent was given, including parole.

(Authority: 38 U.S.C. 7334)

§§ 1.480–1.484 [Reserved]

Disclosures Without Patient Consent

§ 1.485 Medical emergencies.

(a) *General rule.* Under the procedures required by paragraph (c) of this section, patient identifying information from records covered by §§ 1.460 through 1.499 of this part may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.

(b) *Special rule.* Patient identifying information may be disclosed to medical personnel of the Food and Drug Administration (FDA) who assert a reason to believe that the health of any individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction, and that the information will be used for the exclusive purpose

of notifying patients or their physicians of potential dangers.

(c) *Procedures.* Immediately following disclosure, any VA employee making an oral disclosure under authority of this section shall make an accounting of the disclosure in accordance with the Privacy Act (5 U.S.C. 552a(c) and 38 CFR 1.576(c)) and document the disclosure in the patient's records setting forth in writing:

(1) The name and address of the medical personnel to whom disclosure was made and their affiliation with any health care facility;

(2) The name of the individual making the disclosure;

(3) The date and time of the disclosure;

(4) The nature of the emergency (or error, if the report was to FDA);

(5) The information disclosed; and

(6) The authority for making the disclosure (§ 1.485 of this part).

(Authority: 38 U.S.C. 7332(b)(2)(A))

§ 1.486 Disclosure of information related to infection with the human immunodeficiency virus to public health authorities.

(a) In the case of any record which is maintained in connection with the performance of any program or activity relating to infection with the HIV, information may be disclosed to a Federal, State, or local public health authority, charged under Federal or State law with the protection of the public health, and to which Federal or State law requires disclosure of such record, if a qualified representative of such authority has made a written request that such record be provided as required pursuant to such law for a purpose authorized by such law. In the case of a State law, such law must, in order for VA to be able to release patient name and address information in accordance with 38 U.S.C. 5701(f)(2), provide for a penalty or fine or other sanction to be assessed against those individuals who are subject to the jurisdiction of the public health authority but fail to comply with the reporting requirements.

(b) A person to whom a record is disclosed under this section may not redisclose or use such record for a purpose other than that for which the disclosure was made.

(Authority: 38 U.S.C. 7332(b)(2)(C))

§ 1.487 Disclosure of information related to infection with the human immunodeficiency virus to the spouse or sexual partner of the patient.

(a) Subject to paragraph (b) of this section, a physician or a professional counselor may disclose information or

records indicating that a patient is infected with the HIV if the disclosure is made to the spouse of the patient, or to an individual whom the patient has, during the process of professional counseling or of testing to determine whether the patient is infected with such virus, identified as being a sexual partner of such patient.

(b) A disclosure under this section may be made only if the physician or counselor, after making reasonable efforts to counsel and encourage the patient to provide the information to the spouse or sexual partner, reasonably believes that the patient will not provide the information to the spouse or sexual partner and that the disclosure is necessary to protect the health of the spouse or sexual partner.

(c) A disclosure under this section may be made by a physician or counselor other than the physician or counselor referred to in paragraph (b) of this section if such physician or counselor is unavailable by reason of extended absence or termination of employment to make the disclosure.

(Authority: 38 U.S.C. 7332(b))

§ 1.488 Research activities.

Subject to the provisions of 38 U.S.C. 5701, 38 CFR 1.500–1.527, the Privacy Act (5 U.S.C. 552a), 38 CFR 1.575–1.584 and the following paragraphs, patient medical record information covered by §§ 1.460 through 1.499 of this part may be disclosed for the purpose of conducting scientific research.

(a) Information in individually identifiable form may be disclosed from records covered by §§ 1.460 through 1.499 of this part for the purpose of conducting scientific research if the Under Secretary for Health or designee makes a determination that the recipient of the patient identifying information:

(1) Is qualified to conduct the research.

(2) Has a research protocol under which the information:

(i) Will be maintained in accordance with the security requirements of § 1.466 of this part (or more stringent requirements); and

(ii) Will not be redisclosed except as permitted under paragraph (b) of this section.

(3) Has furnished a written statement that the research protocol has been reviewed by an independent group of three or more individuals who found that the rights of patients would be adequately protected and that the potential benefits of the research outweigh any potential risks to patient confidentiality posed by the disclosure of records.

(b) A person conducting research may disclose information obtained under paragraph (a) of this section only back to VA and may not identify any individual patient in any report of that research or otherwise disclose patient identities.

(Authority: 38 U.S.C. 7332(b)(2)(B))

§ 1.489 Audit and evaluation activities.

Subject to the provisions of 38 U.S.C. 5701, 38 CFR 1.500–1.527, the Privacy Act (5 U.S.C. 552a), 38 CFR 1.575–1.584, and the following paragraphs, patient medical records covered by §§ 1.460 through 1.499 of this part may be disclosed outside VA for the purposes of conducting audit and evaluation activities.

(a) *Records not copies.* If patient records covered by §§ 1.460 through 1.499 of this part are not copied, patient identifying information may be disclosed in the course of a review of records on VA facility premises to any person who agrees in writing to comply with the limitations on redisclosure and use in paragraph (d) of this section and:

(1) Where audit or evaluation functions are performed by a State or Federal governmental agency on behalf of VA; or

(2) Who is determined by the VA facility director to be qualified to conduct the audit or evaluation activities.

(b) *Copying of records.* Records containing patient identifying information may be copied by any person who:

(1) Agrees in writing to:

(i) Maintain the patient identifying information in accordance with the security requirements provided in § 1.466 of this part (or more stringent requirements);

(ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and

(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section.

(2) The VA medical facility director determines to be qualified to conduct the audit or evaluation activities.

(c) *Congressional oversight.* Records subject to §§ 1.460 through 1.499 of this part upon written request may be released to congressional committees or subcommittees for program oversight and evaluation if such records pertain to any matter within the jurisdiction of such committee or subcommittee.

(d) *Limitation on disclosure and use.* Records containing patient identifying information disclosed under this section may be disclosed only back to VA and used only to carry out an audit or evaluation purpose, or, to investigate or

prosecute criminal or other activities as authorized by a court order entered under § 1.494 of this part.

(Authority: 38 U.S.C. 7332(b)(2)(B))

Court Orders Authorizing Disclosures and Use

§ 1.490 Legal effect of order.

The records to which §§ 1.460 through 1.499 of this part apply may be disclosed if authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefore. In assessing good cause the court is statutorily required to weigh the public interest and the need for disclosure against the injury to the patient or subject, 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, is required by statute to impose appropriate safeguards against unauthorized disclosure. An order of a court of competent jurisdiction to produce records subject to §§ 1.460 through 1.499 of this part will not be sufficient unless the order reflects that the court has complied with the requirements of 38 U.S.C. 7332(b)(2)(D). Such an order from a Federal court compels disclosure. However, such an order from a State court only acts to authorize the Secretary to exercise discretion pursuant to 38 U.S.C. 5701(b)(5) and 38 CFR 1.511 to disclose such records. It does not compel disclosure.

(Authority: 38 U.S.C. 7332(b)(2)(D))

§ 1.491 Confidential communications.

(a) A court order under §§ 1.490 through 1.499 of this part may authorize disclosure of confidential communications made by a patient to a treatment program in the course of diagnosis, treatment, or referral for treatment only if:

(1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties;

(2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or

(3) The disclosure is in connection with litigation or an administrative

proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.

(Authority: 38 U.S.C. 7334)

§ 1.492 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.

A court order under §§ 1.460 through 1.499 of this part may not authorize qualified personnel, who have received patient identifying information from VA without consent for the purpose of conducting research, audit or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under § 1.495 of this part may authorize disclosure and use of records to investigate or prosecute VA personnel.

(Authority: 38 U.S.C. 7334)

§ 1.493 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.

(a) *Application.* An order authorizing the disclosure of patient records covered by §§ 1.460 through 1.499 of this part for purposes other than criminal investigation or prosecution may be applied for by any person having a legally recognized interest in the disclosure which is sought. The application may be filed separately or as part of a pending civil action in which it appears that the patient records are needed to provide evidence. An application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the patient is the applicant or has given a written consent (meeting the requirements of § 1.475 of this part) to disclosure or the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice.* The patient and VA facility from whom disclosure is sought must be given:

(1) Adequate notice in a manner which will not disclose patient identifying information to other persons; and

(2) An opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on whether the statutory and regulatory criteria for the issuance of the court order are met.

(c) *Review of evidence: Conduct of hearing.* Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers or in some manner which ensures that patient identifying information is not disclosed to anyone other than a party

to the proceeding, the patient, or VA, unless the patient requests an open hearing in a manner which meets the written consent requirements of § 1.475 of this part. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria for entry of order.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find that:

(1) Other ways of obtaining the information are not available or would not be effective; and

(2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

(e) *Content of order.* An order authorizing a disclosure must:

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

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

(3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

(Authority: 38 U.S.C. 7334)

§ 1.494 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.

(a) *Application.* An order authorizing the disclosure or use of patient records covered by §§ 1.460 through 1.499 of this part to criminally investigate or prosecute a patient may be applied for by VA or by any person conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws. The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending criminal action. An application must use a fictitious name such as John Doe, to refer to any patient and may not contain or otherwise disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice and hearing.* Unless an order under § 1.495 of this part is sought with an order under this section, VA must be given:

(1) Adequate notice (in a manner which will not disclose patient identifying information to third parties)

of an application by a person performing a law enforcement function;

(2) An opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order; and

(3) An opportunity to be represented by counsel.

(c) *Review of evidence: Conduct of hearings.* Any oral argument, review of evidence, or hearing on the application shall be held in the judge's chambers or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient, or VA. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria.* A court may authorize the disclosure and use of patient records for the purpose of conducting a criminal investigation or prosecution of a patient only if the court finds that all of the following criteria are met:

(1) The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including, but not limited to, homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.

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

(3) Other ways of obtaining the information are not available or would not be effective.

(4) The potential injury to the patient, to the physician-patient relationship and to the ability of VA to provide services to other patients is outweighed by the public interest and the need for the disclosure.

(5) If the applicant is a person performing a law enforcement function, VA has been represented by counsel independent of the applicant.

(e) *Content of order.* Any order authorizing a disclosure or use of patient records under this section must:

(1) Limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of extremely serious crime or suspected crime specified in the applications; and

(3) Include such other measures as are necessary to limit disclosure and use to the fulfillment on only that public interest and need found by the court.

(Authority: 38 U.S.C. 7332(c))

§ 1.495 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute VA or employees of VA.

(a) *Application.*

(1) An order authorizing the disclosure or use of patient records covered by §§ 1.460 through 1.499 of this part to criminally or administratively investigate or prosecute VA (or employees or agents of VA) may be applied for by an administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over VA activities.

(2) The application may be filed separately or as part of a pending civil or criminal action against VA (or agents or employees of VA) in which it appears that the patient records are needed to provide material evidence. The application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny or the patient has given a written consent (meeting the requirements of § 1.475 of this part) to that disclosure.

(b) *Notice not required.* An application under this section may, in the discretion of the court, be granted without notice. Although no express notice is required to VA or to any patient whose records are to be disclosed, upon implementation of an order so granted VA or the patient must be afforded an opportunity to seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Requirements for order.* An order under this section must be entered in accordance with, and comply with the requirements of, § 1.493(d) and (e) of this part.

(d) *Limitations on disclosure and use of patient identifying information.*

(1) An order entered under this section must require the deletion of patient identifying information from any documents made available to the public.

(2) No information obtained 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 § 1.494 of this part.

(Authority: 38 U.S.C. 7334)

§ 1.496 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of VA.

(a) *Application.* A court order authorizing the placement of an undercover agent or informant in a VA drug or alcohol abuse, HIV infection, or sickle cell anemia treatment program as an employee or patient may be applied for by any law enforcement or prosecutorial agency which has reason to believe that employees or agents of the VA treatment program are engaged in criminal misconduct.

(b) *Notice.* The VA facility director must be given adequate notice of the application and an opportunity to appear and be heard (for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order), unless the application asserts a belief that:

(1) The VA facility director is involved in the criminal activities to be investigated by the undercover agent or informant; or

(2) The VA facility director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.

(c) *Criteria.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find:

(1) There is reason to believe that an employee or agent of a VA treatment program is engaged in criminal activity;

(2) Other ways of obtaining evidence of this criminal activity are not available or would not be effective; and

(3) The public interest and need for the placement of an undercover agent or informant in the VA treatment program outweigh the potential injury to patients of the program, physician-patient relationships and the treatment services.

(d) *Content of order.* An order authorizing the placement of an undercover agent or informant in a VA treatment program must:

(1) Specifically authorize the placement of an undercover agent or an informant;

(2) Limit the total period of the placement to six months;

(3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to criminally investigate or prosecute employees or agents of the VA treatment program; and

(4) Include any other measures which are appropriate to limit any potential disruption of the program by the

placement and any potential for a real or apparent breach of patient confidentiality; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

(e) *Limitation on use of information.* No information obtained by an undercover agent or informant placed under this section may be used to criminally investigate or prosecute any patient or as the basis for an application for an order under § 1.494 of this part.

(Authority: 38 U.S.C. 7334)

§ 1.497–1.499 [Reserved]**§ 1.513 [Amended]**

3. In § 1.513(b)(2) remove the words "Post Office Department" and add in their place, "U.S. Postal Service".

§ 1.513a [Removed]

4. Section § 1.513a is removed.

[FR Doc. 95–30138 Filed 12–12–95; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[PA 081–4012a; FRL–5326–5]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Approval of Stage II Vapor Recovery Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the Commonwealth of Pennsylvania. This revision supplements the approved Pennsylvania Stage II regulation by establishing and requiring appropriate testing and certification of Stage II vapor recovery equipment for affected sources in Pennsylvania. The intended effect of this action is to approve these requirements as a supplement to the Pennsylvania Stage II vapor recovery regulation, Chapter 129.82. Final approval of these supplemental provisions to the Stage II regulation will stop the sanctions clock that was started on June 13, 1994.

DATES: This action will become effective January 22, 1996 unless notice is received on or before January 12, 1996 that adverse or critical comments will be submitted. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Comments may be mailed to Marcia L. Spink, Associate Director, Air Programs, Mailcode 3AT00, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107; the Air and Radiation Docket and Information Center, U.S.

Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Cynthia H. Stahl, (215) 597–9337, at the EPA Region III address above.

SUPPLEMENTARY INFORMATION: On October 26, 1995, the Commonwealth of Pennsylvania submitted a formal revision to its State Implementation Plan (SIP). The SIP revision consists of sections 6.7(b), (c), (h) and section 17(2) of the Pennsylvania Air Pollution Control Act, as amended on June 29, 1992 and effective on July 9, 1992.

These provisions are meant to supplement the existing Pennsylvania Stage II vapor recovery regulation, Chapter 129.82. EPA approved the Stage II regulations in a final limited approval/disapproval rulemaking notice on June 13, 1994 (59 FR 30302). These supplemental provisions correct the deficiencies identified in that rulemaking notice and the proposal, which was published on November 29, 1993 (58 FR 62560). The June 13, 1994 final limited approval/disapproval rulemaking started a sanctions clock that allowed Pennsylvania 18 months to submit material that would correct the deficiencies in the Stage II regulation. This 18 month period ends on January 14, 1996. Final approval of the Stage II regulations will stop this sanctions clock. The submittal of the supplemental provisions that correct the existing deficiency in the Pennsylvania Stage II regulation allows EPA to convert the limited approval/disapproval of the Pennsylvania Stage II regulation to a full approval; thereby halting the sanctions clock.

Summary of SIP Revision

Section 17(2) establishes the effective date of the Pennsylvania Stage II vapor recovery regulations as November 12, 1992. This effective date is consistent with the requirements of section 182 of