

§ 2.3

§ 2.3 Purpose and effect.

(a) *Purpose.* Under the statutory provisions quoted in §§ 2.1 and 2.2, these regulations impose restrictions upon the disclosure and use of alcohol and drug abuse patient records which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program. The regulations specify:

(1) Definitions, applicability, and general restrictions in subpart B (definitions applicable to § 2.34 only appear in that section);

(2) Disclosures which may be made with written patient consent and the form of the written consent in subpart C;

(3) Disclosures which may be made without written patient consent or an authorizing court order in subpart D; and

(4) Disclosures and uses of patient records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders in subpart E.

(b) *Effect.* (1) These regulations prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstance exists under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.

(2) These regulations are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.

(3) Because there is a criminal penalty (a fine—see 42 U.S.C. 290ee-3(f), 42 U.S.C. 290dd-3(f) and 42 CFR 2.4) for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute (see *M. Kraus & Brothers v. United States*, 327 U.S. 614, 621-22, 66 S. Ct. 705, 707-08 (1946)).

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§ 2.4 Criminal penalty for violation.

Under 42 U.S.C. 290ee-3(f) and 42 U.S.C. 290dd-3(f), any person who violates any provision of those statutes or these regulations shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

§ 2.5 Reports of violations.

(a) The report of any violation of these regulations may be directed to the United States Attorney for the judicial district in which the violation occurs.

(b) The report of any violation of these regulations by a methadone program may be directed to the Regional Offices of the Food and Drug Administration.

Subpart B—General Provisions

§ 2.11 Definitions.

For purposes of these regulations:

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

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.

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 which is made for the purpose of treatment or referral for treatment.

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.

Informant means an individual:

(a) Who is a patient or employee of a program or who becomes a patient or employee of a program at the request of a law enforcement agency or official; and

(b) Who at the request of a law enforcement agency or official observes one or more patients or employees of

the program for the purpose of reporting the information obtained to the law enforcement agency or official.

Patient means any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program.

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 program, if that number does not consist of, or contain numbers (such as a 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 program.

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

Program means:

(a) An individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(b) An identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(c) 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. (See § 2.12(e)(1) for examples.)

Program director means:

(a) In the case of a program which is an individual, that individual:

(b) In the case of a program which is an organization, the individual designated as director, managing director, or otherwise vested with authority to

act as chief executive of the organization.

Qualified service organization means a person which:

(a) Provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

(b) Has entered into a written agreement with a program under which that person:

(1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the programs, it is fully bound by these regulations; and

(2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

Records means any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.

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 family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

Treatment means the management and care of a patient suffering from alcohol or drug abuse, a condition which is identified as having been caused by that abuse, or both, in order to reduce or eliminate the adverse effects upon the patient.

Undercover agent means an officer of any Federal, State, or local law enforcement agency who enrolls in or becomes an employee of a program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

[52 FR 21809, June 9, 1987, as amended by 60 FR 22297, May 5, 1995]

§ 2.12 Applicability.

(a) *General*—(1) *Restrictions on disclosure*. The restrictions on disclosure in