

§ 2.12

emails, voice mails, and texts). For the purpose of the regulations in this part, records include both paper and electronic records.

Substance use disorder means a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. For the purposes of the regulations in this part, this definition does not include tobacco or caffeine use.

Third-party payer means an individual or entity who pays and/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 the patient's family or on the basis of the patient's eligibility for federal, state, or local governmental benefits.

Treating provider relationship means that, regardless of whether there has been an actual in-person encounter:

(1) A patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treated, or agrees to accept consultation, for any condition by an individual or entity, and;

(2) The individual or entity undertakes or agrees to undertake diagnosis, evaluation, and/or treatment of the patient, or consultation with the patient, for any condition.

Treatment means the care of a patient suffering from a substance use disorder, a condition which is identified as having been caused by the substance use disorder, or both, in order to reduce or eliminate the adverse effects upon the patient.

Undercover agent means any federal, state, or local law enforcement agency or official who enrolls in or becomes an employee of a part 2 program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

Withdrawal management means the use of pharmacotherapies to treat or attenuate the problematic signs and symptoms arising when heavy and/or prolonged substance use is reduced or discontinued.

42 CFR Ch. I (10–1–18 Edition)

§ 2.12 Applicability.

(a) *General*—(1) *Restrictions on disclosure*. The restrictions on disclosure in the regulations in this part apply to any information, whether or not recorded, which:

(i) Would identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person; and

(ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972 (part 2 program), or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (part 2 program); or if obtained before the pertinent date, is maintained by a part 2 program after that date as part of an ongoing treatment episode which extends past that date; for the purpose of treating a substance use disorder, making a diagnosis for that treatment, or making a referral for that treatment.

(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 (42 U.S.C. 290dd-2(c)) applies to any information, whether or not recorded, which is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972 (part 2 program), or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (part 2 program); or if obtained before the pertinent date, is maintained by a part 2 program after that date as part of an ongoing treatment episode which extends past that date; for the purpose of treating a substance use disorder, making a diagnosis for the treatment, or making a referral for the treatment.

(b) *Federal assistance*. A program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (2) of this section relating to the Department of Veterans Affairs and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or

other authorization granted by any department or agency of the United States including but not limited to:

- (i) Participating provider in the Medicare program;
- (ii) Authorization to conduct maintenance treatment or withdrawal management; or
- (iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of substance use disorders;

(3) It is supported by funds provided by any department or agency of the United States by being:

- (i) A recipient of federal financial assistance in any form, including financial assistance which does not directly pay for the substance use disorder diagnosis, treatment, or referral for treatment; or
- (ii) Conducted by a state or local government unit which, through general or special revenue sharing or other forms of assistance, receives federal funds which could be (but are not necessarily) spent for the substance use disorder program; or

(4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(c) *Exceptions*— (1) *Department of Veterans Affairs*. These regulations do not apply to information on substance use disorder patients maintained in connection with the Department of Veterans Affairs' provision of hospital care, nursing home care, domiciliary care, and medical services under Title 38, U.S.C. Those records are governed by 38 U.S.C. 7332 and regulations issued under that authority by the Secretary of Veterans Affairs.

(2) *Armed Forces*. The regulations in this part apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

- (i) Any interchange of that information within the Armed Forces; and
- (ii) Any interchange of that information between the Armed Forces and

those components of the Department of Veterans Affairs furnishing health care to veterans.

(3) *Communication within a part 2 program or between a part 2 program and an entity having direct administrative control over that part 2 program*. The restrictions on disclosure in the regulations in this part do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of patients with substance use disorders if the communications are:

- (i) Within a part 2 program; or
- (ii) Between a part 2 program and an entity that has direct administrative control over the program.

(4) *Qualified service organizations*. The restrictions on disclosure in the regulations in this part do not apply to communications between a part 2 program and a qualified service organization of information needed by the qualified service organization to provide services to the program.

(5) *Crimes on part 2 program premises or against part 2 program personnel*. The restrictions on disclosure and use in the regulations in this part do not apply to communications from part 2 program personnel to law enforcement agencies or officials which:

- (i) Are directly related to a patient's commission of a crime on the premises of the part 2 program or against part 2 program personnel 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, and that individual's last known whereabouts.

(6) *Reports of suspected child abuse and neglect*. The restrictions on disclosure and use in the regulations in this part do not apply to the reporting under state law of incidents of suspected child abuse and neglect to the appropriate state or local authorities. However, the restrictions continue to apply to the original substance use disorder patient records maintained by the part 2 program including their disclosure

§ 2.12

42 CFR Ch. I (10–1–18 Edition)

and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

(d) *Applicability to recipients of information*— (1) *Restriction on use of information*. The restriction on the use of any information subject to the regulations in 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 a part 2 program, regardless of the status of the person obtaining the information or whether the information was obtained in accordance with the regulations in 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 § 2.17) or through patient access (see § 2.23) is subject to the restriction on use.

(2) *Restrictions on disclosures*—(i) *Third-party payers, administrative entities, and others*. The restrictions on disclosure in the regulations in this part apply to:

(A) Third-party payers with regard to records disclosed to them by part 2 programs or under § 2.31(a)(4)(iii)(A);

(B) Entities having direct administrative control over part 2 programs with regard to information that is subject to the regulations in this part communicated to them by the part 2 program under paragraph (c)(3) of this section; and

(C) Individuals or entities who receive patient records directly from a part 2 program or other lawful holder of patient identifying information and who are notified of the prohibition on re-disclosure in accordance with § 2.32.

(ii) [Reserved]

(e) *Explanation of applicability*—(1) *Coverage*. These regulations cover any information (including information on referral and intake) about patients receiving diagnosis, treatment, or referral for treatment for a substance use disorder created by a part 2 program. Coverage includes, but is not limited to, those treatment or rehabilitation

programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as providing, and provide substance use disorder diagnosis, treatment, or referral for treatment. However, the regulations in this part would not apply, for example, to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose, unless the primary function of such personnel is the provision of substance use disorder diagnosis, treatment, or referral for treatment and they are identified as providing such services or the emergency room has promoted itself to the community as a provider of such services.

(2) *Federal assistance to program required*. If a patient's substance use disorder diagnosis, treatment, or referral for treatment is not provided by a part 2 program, that patient's record is not covered by the regulations in this part. Thus, it is possible for an individual patient to benefit from federal support and not be covered by the confidentiality regulations because the program in which the patient is enrolled is not federally assisted as defined in paragraph (b) of this section. For example, if a federal court placed an individual in a private for-profit program and made a payment to the program on behalf of that individual, that patient's record would not be covered by the regulations in this part unless the program itself received federal assistance as defined by paragraph (b) of this section.

(3) *Information to which restrictions are applicable*. Whether a restriction applies to use or disclosure affects the type of information which may be disclosed. The restrictions on disclosure apply to any information which would identify a patient as having or having had a substance use disorder. The restriction on use of information to bring criminal charges against a patient for a crime applies to any information obtained by the part 2 program for the purpose of diagnosis, treatment, or referral for treatment of patients with substance use disorders. (Note that restrictions on use and disclosure apply to recipients of information under paragraph (d) of this section.)

(4) *How type of diagnosis affects coverage.* These regulations cover any record of a diagnosis identifying a patient as having or having had a substance use disorder which is initially prepared by a part 2 provider in connection with the treatment or referral for treatment of a patient with a substance use disorder. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by the regulations in this part. The following are not covered by the regulations in this part:

(i) Diagnosis which is made solely for the purpose of providing evidence for use by law enforcement agencies or officials; or

(ii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved does not have a substance use disorder (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).

§ 2.13 Confidentiality restrictions and safeguards.

(a) *General.* The patient records subject to the regulations in this part may be disclosed or used only as permitted by the regulations in this part 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 the regulations in this part 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 the regulations in this part apply whether or not the part 2 program or other lawful holder of the patient identifying information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement agency or official or other government official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by the regulations in this part.

(c) *Acknowledging the presence of patients: Responding to requests.* (1) The presence of an identified patient in a health care facility or component of a health care facility which is publicly

identified as a place where only substance use disorder diagnosis, treatment, or referral for treatment is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of this part or if an authorizing court order is entered in accordance with subpart E of this part. The regulations permit acknowledgement of the presence of an identified patient in a health care facility or part of a health care facility if the health care facility is not publicly identified as only a substance use disorder diagnosis, treatment, or referral for treatment facility, and if the acknowledgement does not reveal that the patient has a substance use disorder.

(2) Any answer to a request for a disclosure of patient records which is not permissible under the regulations in 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 a substance use disorder. An inquiring party may be provided a copy of the regulations in this part and advised that they restrict the disclosure of substance use disorder patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient.

(d) *List of disclosures.* Upon request, patients who have consented to disclose their patient identifying information using a general designation pursuant to § 2.31(a)(4)(iii)(B)(3) must be provided a list of entities to which their information has been disclosed pursuant to the general designation.

(1) Under this paragraph (d), patient requests:

(i) Must be made in writing; and

(ii) Are limited to disclosures made within the past two years;

(2) Under this paragraph (d), the entity named on the consent form that discloses information pursuant to a patient's general designation (the entity that serves as an intermediary, as described in § 2.31(a)(4)(iii)(B)) must:

(i) Respond in 30 or fewer days of receipt of the written request; and

(ii) Provide, for each disclosure, the name(s) of the entity(-ies) to which the disclosure was made, the date of the disclosure, and a brief description of