

42 CFR 2 Part 2 (“Part 2”): Confidentiality of Alcohol and Drug Abuse Patient Records

In 1970, Congress passed the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act,¹ part of which contained general rules establishing the confidentiality of alcohol abuse patient records.² Congress subsequently passed the Drug Abuse Prevention, Treatment, and Rehabilitation Act in 1972,³ a law with identical confidentiality provisions applicable to drug abuse patient records.⁴ Both Acts authorized the Secretary of Health and Human Services to develop regulations restricting the disclosure and use of substance abuse patient records.⁵ In 1987, the Secretary issued such regulations,⁶ commonly referred to as “Part 2,” describing the circumstances in which information about a substance abuse patient’s treatment may be disclosed and used with and without the patient’s consent.

These Acts and the Part 2 regulations limit the availability of substance abuse records to insure that individuals in a treatment program are not more vulnerable with respect to their privacy than those who do not seek treatment.⁷ Covered information may only be disclosed or used as permitted by these regulations, and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceeding conducted by any federal, state, or local authority.⁸

1.) Applicability of the Part 2 Regulations

a.) Definitions

Substance abuse, as used in this summary, means alcohol or drug abuse, or both. *Alcohol use* is the consumption of any alcoholic beverage, while *drug use* is the non-medicinal use of a psychoactive substance. *Alcohol*⁹ and *drug abuse*¹⁰ are the use of the relevant substance in a manner that impairs the physical, mental, emotional, or social well-being of the user.

A substance abuse *diagnosis* is a reference to an individual’s substance abuse or to a condition caused by that abuse for purposes of treatment or referral for treatment,¹¹ even if the diagnosis is not ultimately used for such purposes.¹² However, *diagnosis* does not include:

¹ 42 U.S.C. §§ 4541, et seq. (2013).

² 42 U.S.C. § 4582, as amended and transferred to the Public Health Service Act § 523, *codified at* 42 U.S.C. § 290dd-3 (2013).

³ 21 U.S.C. §§ 1101, et seq. (2013).

⁴ 21 U.S.C. § 1175, as amended and transferred to the Public Health Service Act § 527, *codified at* 42 U.S.C. § 290ee-3 (2013).

⁵ 42 U.S.C. § 290dd-3(g), as amended (alcohol abuse records) and § 290ee-3(g), as amended (drug abuse records).

⁶ 52 Fed. Reg. 21809 (June 9, 1987), *codified at* 42 C.F.R. §§ 2.1, et seq. (2013).

⁷ 42 CFR § 2.3(b)(2).

⁸ 42 CFR § 2.13(a).

⁹ 42 CFR § 2.11 at “Alcohol abuse.”

¹⁰ 42 CFR § 2.11 at “Drug abuse.”

¹¹ 42 CFR § 2.11 at “Diagnosis.”

¹² 42 CFR § 2.12(e)(4).

- A diagnosis of drug overdose or alcohol intoxication that clearly shows that the individual involved is not a substance abuser (such as, for example, involuntary consumption or a reaction to a prescribed dosage of a drug);¹³ or
- Diagnosis made solely to provide evidence for use by law enforcement authorities.¹⁴

Substance abuse *treatment* is the management and care of a patient suffering from substance abuse or a condition caused by that abuse, or both, in order to reduce or eliminate the patient's adverse effects.¹⁵

b.) Programs Subject to the Regulations

A substance abuse program is any of the following:

- An identified unit or program within a general medical facility that holds itself out as providing, and provides, substance abuse diagnosis, treatment, or referral for treatment;¹⁶
- Medical personnel or other staff in a general medical care facility whose primary function is the provision of substance abuse diagnosis, treatment, or referral for treatment and who are identified as such providers;¹⁷ and
- An entity (other than a general medical facility) that holds itself out as providing, and provides, substance abuse diagnosis, treatment, or referral.¹⁸ This could include:
 - Treatment or rehabilitation programs;
 - Employee assistance programs;
 - School-based programs; or
 - Private practitioners.¹⁹

Even if a substance abuse program holds itself out as, and actually is, a provider of substance abuse services, the Part 2 regulations only apply to the following types of programs:

- Programs conducted in whole or in part (directly or by contract) by any United States department or agency;²⁰
- Programs being carried out under a license, certification, registration, or other authorization granted by any US department or agency – this includes entities that are certified as Medicare providers, entities authorized to conduct methadone maintenance treatment, and entities registered with the Drug Enforcement Agency (DEA) to dispense a controlled substance used in the treatment of substance abuse (e.g., entities with a DEA number);²¹
- Programs supported by funds provided by any US department or agency as a recipient of federal financial assistance in any form;²²
- Programs conducted by a state or local government unit that receives federal funds that *could be* (but are not necessarily) spent for the substance abuse program;²³ or

¹³ 42 CFR § 2.12(e)(4)(ii).

¹⁴ 42 CFR § 2.12(e)(4)(i).

¹⁵ 42 CFR § 2.11 at "Treatment."

¹⁶ 42 CFR § 2.11 at ¶ (b) of "Program."

¹⁷ 42 CFR § 2.11 at ¶ (c) of "Program."

¹⁸ 42 CFR § 2.11 at ¶ (a) of "Program."

¹⁹ 42 CFR § 2.12(e)(1).

²⁰ 42 CFR § 2.12(b)(1).

²¹ 42 CFR § 2.12(b)(2) (this includes certification of provider status under Medicare (b)(2)(i), authorization to conduct methadone maintenance treatment (b)(2)(ii), and registration to dispense a controlled substance under the Controlled Substances Act to the extent that the substance is being used in the treatment of alcohol or drug abuse (b)(2)(iii)).

²² 42 CFR § 2.12(b)(3)(i) (including financial assistance that does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities).

²³ 42 CFR § 2.12(b)(3)(ii).

- Programs allowed federal income tax deductions for contributions to the program or granted federal tax-exempt status by the IRS.²⁴

In sum, only **federally assisted** programs that hold themselves out as providing (and actually provide) substance abuse diagnosis, treatment, or referral for such treatment are subject to Part 2.²⁵ Given the broad definition of “federally assisted” (to include Medicare providers and entities with a DEA number), nearly all programs are considered federally assisted. The only programs and providers that would not fall under this definition are those that are for-profit and which only accept the privately insured or individuals who pay out of pocket for all treatment received.

c.) Individuals Protected by Part 2

These restrictions protect *substance abuse patients*, which includes:²⁶

- Any individual who has applied for or been given diagnosis or treatment for substance abuse at a federally assisted program; and
- Any individual who, after arrest on a criminal charge, is identified as substance abuser in order to determine his eligibility to participate in a federally assisted program.

The restrictions on use and disclosure cover any individual who has been a substance abuse patient of a federally assisted program, even after s/he ceases to be a patient.²⁷

d.) Information Covered by Part 2

The restrictions on use and disclosure apply to any information, whether or not recorded, that is obtained by a federally assisted program for purposes of treating substance abuse, or for making a diagnosis or referral for such treatment.²⁸ This includes information on referral and intake.²⁹

2.) Part 2 Restrictions

a.) Disclosure

A patient must give written consent for all disclosures³⁰ of covered information that would identify the patient as a substance abuser (directly, by reference to other publicly available information, or through verification of such identification by another person), except in limited circumstances.³¹ This requirement also applies to any entity that receives patient records directly from a program, if the receiving entity is properly notified of the restriction on re-disclosure.³² The following entities are also subject to this requirement, whether or not they are notified of the restrictions on re-disclosure:³³

- Third party payers;³⁴ and
- Administrative entities (as discussed below in section 3(c)).

²⁴ 42 CFR § 2.12(b)(4).

²⁵ 42 CFR § 2.12(e)(2).

²⁶ 42 CFR § 2.11 at “Patient.”

²⁷ 42 CFR § 2.1 (referencing § 290ee-3(d)); 42 CFR § 2.2 (referencing § 290dd-3(d)).

²⁸ 42 CFR § 2.12(a)(1)(ii), (2).

²⁹ 42 CFR § 2.12(e)(1).

³⁰ Disclosure includes communicating patient identifying information, affirmatively verifying another person’s communication of patient identifying information, or communicating any information from the record of a patient who has been identified (42 CFR § 2.11, at “Disclose or disclosure”).

³¹ 42 CFR § 2.1(a) (referencing § 290ee-3(a)); 42 CFR § 2.2(a) (referencing § 290dd-3(a)); 42 CFR § 2.12(a)(1).

³² 42 CFR § 2.12(d)(2)(iii) (Note: the relevant re-disclosure provision is located at 42 CFR § 2.32 and is discussed in Section 4).

³³ 42 CFR § 2.12(d)(2).

³⁴ An entity 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 (42 CFR § 2.11, at “Third party payer”).

Any information that is disclosed in accordance with the Part 2 regulations must be limited to the information that is necessary to carry out the intended purpose of the disclosure.³⁵ If an entity receives an impermissible request to disclose covered information, its response may not affirmatively reveal that an identified individual has been or is a patient (but may reveal that an identified individual is not and never has been a patient, if applicable).³⁶

b.) Use

Use of covered information to initiate or substantiate criminal charges against a patient or to conduct any criminal investigation is prohibited absent an appropriate court order.³⁷ This restriction also applies to any entity that obtains information from a federally assisted program, regardless of the entity's status or of whether the information was properly obtained.³⁸

c.) Other Requirements

The restrictions on disclosure and use apply in all circumstances, whether or not the holder of the information believes (or knows) that the entity seeking the information:³⁹

- 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 that is not permitted by these regulations.

1. Acknowledging the presence of a patient

If an entity is publicly identified as a place where only substance abuse services are provided, the fact that a patient is present at the entity may only be acknowledged if the patient consents in writing or an authorizing court order has been entered.⁴⁰ If an entity is not publicly identified as a place where only substance abuse services are provided, the fact that a patient is present at the entity may be acknowledged, as long as such acknowledgement does not reveal that the patient is a substance abuser.

2. Patient Identification

A patient may not be required to carry anything that would identify him/her as a substance abuser when off program premises, but may be required to use or carry such identification on program premises.⁴¹

3. Physical Security of Records

When not in use, written records covered by Part 2 regulations must be maintained in a secure room, locked file cabinet, safe, or other similar container.⁴² Programs must have written procedures regulating access to and use of such records.⁴³

4. Program Discontinuation or Acquisition

³⁵ 42 CFR § 2.13(a).

³⁶ 42 CFR § 2.13(c)(2).

³⁷ 42 CFR § 2.1(c) (referencing § 290ee-3(c)); 42 CFR § 2.2(c) (referencing § 290dd-3(c)); 42 CFR § 2.12(a)(2).

³⁸ 42 CFR § 2.12(d)(1).

³⁹ 42 CFR § 2.13(b).

⁴⁰ 42 CFR § 2.13(c)(1).

⁴¹ 42 CFR § 2.18.

⁴² 42 CFR § 2.16(a).

⁴³ 42 CFR § 2.16(b).

When a program closes or is taken over/acquired by another program, it must purge patient identifying information from its records or destroy those records unless:

- The patient gives written consent to transfer his/her records to another program.⁴⁴ The manner of obtaining such consent must minimize the likelihood that patient identifying information will be disclosed to a third party; or
- There is a legal requirement that the records be kept for a specified period beyond the actual date the program closes or is acquired.⁴⁵ In this case, the records must be placed in sealed envelopes or containers and labeled with the following statement: “Records of [program name] required to be maintained under [relevant legal authority] until a date not later than [appropriate date].”⁴⁶ The records remain subject to Part 2 regulations and must be held by a responsible person and destroyed as soon as possible after the retention period ends.⁴⁷

5. Relationship to State Law

If a state law prohibits a disclosure or use that is permitted by the Part 2 regulations, the state law’s stricter requirements apply.⁴⁸ No state law may authorize or compel a disclosure that is prohibited by Part 2.

3.) Regulations Do Not Apply

There are certain situations when substance abuse patient information can be disclosed or used without the patient’s written consent, which are discussed in more detail below in section 4. There are also seven circumstances in which some or all of the regulations do not apply, which are:

a.) *Veteran’s Administration*

The VA provides for medical services as well as hospital, nursing home, and domiciliary care for veterans who have a service-connected disability.⁴⁹ The Part 2 regulations do not apply to substance abuse patient information maintained in connection with the VA’s provisions of these services.⁵⁰ The VA operates under separate rules governing the confidentiality of such information.⁵¹

b.) *Armed Forces*

Substance abuse information obtained by the Armed Forces during the time a patient was subject to the Uniform Code of Military Justice⁵² is generally protected by Part 2 regulations.⁵³ However, the Part 2

⁴⁴ 42 CFR § 2.19(a)(1).

⁴⁵ 42 CFR § 2.19(a)(2).

⁴⁶ 42 CFR § 2.19(b)(1).

⁴⁷ 42 CFR § 2.19(b)(2).

⁴⁸ 42 CFR § 2.20.

⁴⁹ See generally 38 USC Chapter 17 (§§ 1701 – 1787)

⁵⁰ 42 CFR § 2.12(c)(1).

⁵¹ See 38 USC § 7332 (note that the Part 2 regulations reference 38 USC § 4132 – this section was renumbered as current § 7332 in 1991).

⁵² This includes: all active duty members of the Uniformed services of the United States; members of the military Reserve Components serving as Full-Time Support Personnel or as part-time reservists performing full-time active duty for a specific period or performing Inactive Duty; soldiers and airmen in the US National Guard if activated in a Federal capacity by a Presidential Executive Order or during their Annual Training periods; cadets and midshipmen at the US Military, Naval, Air Force, and Coast Guard Academies; retired members of the Uniformed services who are entitled to retirement pay; prisoners of war and detained medical personnel and chaplains in the custody of US armed forces; and persons in custody of the US armed forces serving a sentence imposed by a court-martial (Article 2 of the UCMJ).

⁵³ 42 CFR § 2.12(c)(2).

regulations do not apply to exchanges of such information within the Armed Forces⁵⁴ or between the Armed Forces and the VA.⁵⁵

c.) Program Communications

When substance abuse program personnel need substance abuse information to perform their duties, the Part 2 restrictions on disclosure do not apply to the communication of that information between or among such personnel⁵⁶ or between a program and an entity with direct administrative control over the program.⁵⁷ Entities with direct administrative control are subject to the Part 2 disclosure restrictions with respect to the information they receive from programs.⁵⁸

d.) Qualified Service Organizations

A QSO is an entity that provides professional services (e.g., data processing, dosage preparation, legal services, etc.) or services to prevent or treat child abuse or neglect to or for a substance abuse program.⁵⁹ A QSO must have a written agreement with the program in which the QSO agrees to be bound by the Part 2 regulations⁶⁰ and to resist any efforts to obtain access to patient records in judicial proceedings, except as permitted by Part 2.⁶¹ When a QSO needs patient information to provide services, the Part 2 restrictions on disclosure do not apply to the communication of that information between the program and the QSO.⁶²

e.) Crimes

When a substance abuse patient commits or threatens to commit a crime on program premises or against personnel, the Part 2 restrictions do not apply to communications from program personnel to law enforcement officers that are directly related to such an incident or threat.⁶³ The information disclosed must be limited to the circumstances of the incident, and may include the individual's patient status, name and address, and last known whereabouts.⁶⁴

f.) Child Abuse and Neglect Reporting

If state law permits or requires reporting of suspected child abuse and neglect, the Part 2 restrictions do not apply to such reporting.⁶⁵ However, the restrictions continue to apply to the original patient records maintained by the program, including restrictions on their disclosure and use for any legal proceedings that arise out of a report.

g.) Vital Statistics

If state law mandates the collection of death or other vital statistics or permits inquiries into cause of death, the Part 2 restrictions do not apply to disclosures of information relating to a patient's cause of death for these purposes.⁶⁶

4.) Written Consent

⁵⁴ 42 CFR § 2.1 (referencing § 290ee-3(e)(1)); 42 CFR § 2.2 (referencing §290dd-3(e)(1)); 42 CFR § 2.12(c)(2)(i)

⁵⁵ 42 CFR § 2.1 (referencing § 290ee-3(e)(1)) 42 CFR § 2.2. (referencing § 290dd-3(e)(2)); 42 CFR § 2.12(c)(2)(ii)

⁵⁶ 42 CFR § 2.12(c)(3)(i).

⁵⁷ 42 CFR § 2.12(c)(3)(ii).

⁵⁸ 42 CFR § 2.12(d)(2)(ii).

⁵⁹ 42 CFR § 2.11, at ¶ (a) of "Qualified service organization."

⁶⁰ 42 CFR § 2.11, at ¶ (b)(1) of "Qualified service organization."

⁶¹ 42 CFR § 2.11, at ¶ (b)(2) of "Qualified service organization."

⁶² 42 CFR § 2.12(c)(4).

⁶³ 42 CFR § 2.12(c)(5)(i).

⁶⁴ 42 CFR § 2.12(c)(5)(ii).

⁶⁵ 42 CFR § 2.1 (referencing §290ee-3(e)); 42 CFR § 2.2 (referencing § 290dd-3(e)); 42 CFR § 2.12(c)(6).

⁶⁶ 42 CFR § 2.15(b)(1).

If a patient consents to a disclosure of his/her records, a program may disclose those records in accordance with that consent to any named individual or organization.⁶⁷ Disclosures to central registries and in connection with criminal justice referrals must meet different requirements, discussed below in Section 4(d)(4).

a.) Required Elements

There are nine required elements of a written consent to a disclosure, which are:

- 1) The name/general designation of the program/person permitted to make the disclosure.⁶⁸
- 2) The name/title of the individual or the organization to which disclosure is to be made.⁶⁹
- 3) The name of the patient.⁷⁰
- 4) The purpose of the disclosure.⁷¹
- 5) How much and what kind of information is to be disclosed.⁷²
- 6) The signature of the patient and/or the patient's authorized representative, as required.⁷³
- 7) The date on which the consent is signed.⁷⁴
- 8) A statement that the consent may be revoked at any time except where the entity originally permitted to make the disclosure has already acted in reliance on the consent.⁷⁵
- 9) The date, event, or condition that the consent will expire, which must insure that consent only lasts as long as reasonably necessary to accomplish the purpose of the disclosure.⁷⁶

b.) Consent Invalid

A written consent form is invalid if:

- It has expired;⁷⁷
- Substantially fails to conform to any of the requirements set forth above;⁷⁸
- Is known to have been revoked;⁷⁹ or
- Is known, or by reasonable effort could be known, by the record-holder to be materially false.⁸⁰

c.) Notification of the Restriction on Re-Disclosure

Each disclosure made with the patient's written consent must be accompanied by the following written statement:⁸¹ "This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). 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 42 CFR part 2. 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."

⁶⁷ 42 CFR § 2.33.

⁶⁸ 42 CFR § 2.31(a)(1).

⁶⁹ 42 CFR § 2.31(a)(2).

⁷⁰ 42 CFR § 2.31(a)(3).

⁷¹ 42 CFR § 2.31(a)(4).

⁷² 42 CFR § 2.31(a)(5).

⁷³ 42 CFR § 2.31(a)(6).

⁷⁴ 42 CFR § 2.31(a)(7).

⁷⁵ 42 CFR § 2.31(a)(8).

⁷⁶ 42 CFR § 2.31(a)(9).

⁷⁷ 42 CFR § 2.31(c)(1).

⁷⁸ 42 CFR § 2.31(c)(2).

⁷⁹ 42 CFR § 2.31(c)(3).

⁸⁰ 42 CFR § 2.31(c)(4).

⁸¹ 42 CFR § 2.32.

d.) Special Consent Circumstances

1. Minors

State law generally determines the applicability of the Part 2 regulations to minors. The age of majority is set by state law, and a minor is an individual who has not reached that age.⁸² If there is no such state law, the age of majority is eighteen years old.

- i. **State Law Granting Capacity to Minor.** If the state grants a minor the legal capacity to apply for and obtain substance abuse treatment, only the minor patient may consent to disclosure of his/her information.⁸³ This applies to disclosures to the minor's parent/guardian for the purpose of obtaining payment. A program may refuse to treat a minor until s/he consents to a disclosure necessary to obtain payment, unless a law requires that the program provide services even if the patient cannot pay.
- ii. **State Law Requiring Consent of Parent or Guardian.** If the state requires that an adult representing the minor give consent in order for the minor to obtain substance abuse treatment, both the minor and his/her representative must consent to disclosures of the minor's information.⁸⁴ The fact that a minor has applied for treatment may only be disclosed to his/her representative if the minor gives written consent for the disclosure⁸⁵ or if the program's director determines that the minor does not have the capacity to make a rational choice about whether or not to consent⁸⁶ because of his/her extreme youth or mental or physical condition.⁸⁷

2. Incompetent Patients

If a patient has been legally declared incompetent to manage his/her affairs (other than because of age), the person authorized under state law to act on the patient's behalf may give any consent required by Part 2.⁸⁸

3. Deceased Patients

Disclosures of information identifying a deceased patient as a substance abuser (other than those relating to cause of death, discussed above in Section 3(g)) are subject to Part 2.⁸⁹ Where written consent for a disclosure is required, consent may be given by a personal representative appointed under state law. If there is no such appointment, consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family.

4. Disclosures to Central Registries

A *central registry*⁹⁰ is an organization that obtains patient identifying information from two or more member programs⁹¹ about individuals applying for maintenance⁹² or detoxification treatment.⁹³

⁸² 42 CFR § 2.14(a).

⁸³ 42 CFR § 2.14(b).

⁸⁴ 42 CFR § 2.14(c)(1).

⁸⁵ 42 CFR § 2.14(c)(2)(i).

⁸⁶ 42 CFR § 2.14(c)(2)(ii).

⁸⁷ 42 CFR § 2.14(d)(1).

⁸⁸ 42 CFR § 2.15(a)(1).

⁸⁹ 42 CFR § 2.15(b)(2).

⁹⁰ 42 CFR § 2.34(a), at "Central Registry."

⁹¹ A member program is a detoxification or maintenance treatment program that 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 (42 CFR § 2.34, at "Member program").

⁹² Maintenance treatment is the dispensing of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs (42 CFR § 2.34, at "Maintenance treatment").

A program may disclose patient records to a central registry or to any detoxification or maintenance treatment program within 200 miles to prevent the multiple enrollment of a patient.⁹⁴ The disclosure must be:

- Made at one of the following times:
 - The patient is accepted for treatment;⁹⁵
 - The type or dosage of the drug is changed;⁹⁶ or
 - The treatment is interrupted, resumed, or terminated.⁹⁷
- Limited to the following information:
 - Patient identifying information;⁹⁸
 - Type and dosage of the drug;⁹⁹ and
 - Relevant dates.¹⁰⁰
- Made with the patient's written consent meeting all regular requirements, except that:
 - The consent must list the name and address of each central registry and each known treatment program to which a disclosure will be made;¹⁰¹ and
 - The consent may authorize disclosures to any treatment program within 200 miles that is unknown at the time consent is given without naming any such program.¹⁰²

A central registry or detoxification or maintenance program may only disclose or use patient identifying information to prevent multiple enrollments, unless authorized by court order.¹⁰³ When a member program asks a central registry if an identified patient is enrolled in another member program, the registry may disclose the name, address, and phone number of the member program(s) in which the patient is already enrolled to the inquiring member program¹⁰⁴ and vice versa.¹⁰⁵ Member programs may communicate with each other to verify information and to prevent or eliminate multiple enrollments. A detoxification or maintenance treatment program that has received a disclosure and determined that the patient is already enrolled may communicate with the disclosing program to verify information and to prevent or eliminate any multiple enrollments.¹⁰⁶

5. Disclosures in Connection with Criminal Justice Referrals

A program may disclose patient information to persons within the criminal justice system who have required that the patient participate in the program as a condition of the resolution of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

- The disclosure is made only to those individuals within the criminal justice system who need the information to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient or parole officers supervising the patient);¹⁰⁷ and

⁹³ Detoxification treatment is 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 (42 CFR § 2.34, at "Detoxification treatment").

⁹⁴ 42 CFR § 2.34(b).

⁹⁵ 42 CFR § 2.34(b)(1)(i).

⁹⁶ 42 CFR § 2.34(b)(1)(ii).

⁹⁷ 42 CFR § 2.34(b)(1)(iii).

⁹⁸ 42 CFR § 2.34(b)(2)(i).

⁹⁹ 42 CFR § 2.34(b)(2)(ii).

¹⁰⁰ 42 CFR § 2.34(b)(2)(iii).

¹⁰¹ 42 CFR § 2.34(b)(3)(i).

¹⁰² 42 CFR § 2.34(b)(3)(ii).

¹⁰³ 42 CFR § 2.34(c).

¹⁰⁴ 42 CFR § 2.34(d)(1).

¹⁰⁵ 42 CFR § 2.34(d)(2).

¹⁰⁶ 42 CFR § 2.34(e).

¹⁰⁷ 42 CFR § 2.35(a)(1).

- The patient has signed a valid written consent that includes all the elements described above in Section 4(a), not including the statement that the consent is subject to revocation at any time, as well as the following additional information:¹⁰⁸
 - The period during which the consent remains in effect. This period must be reasonable, taking into account the following:
 - The anticipated length of the treatment;¹⁰⁹
 - The type of criminal proceeding involved, the need for the information in connection with the final resolution of that proceeding, and when the final resolution will occur;¹¹⁰ and
 - Other factors the program, patient, and the person(s) who will receive the disclosure consider pertinent.¹¹¹
 - A statement that the consent is revocable after a specific time period or upon the occurrence of a specific event.¹¹² The consent may become revocable no later than the patient's conditional release or other action in connection with which consent was given.

A person who receives patient information in connection with a criminal justice referral may re-disclose and use it only to carry out that person's official duties related to the patient's conditional release or other action in connection with which the consent was given.¹¹³

5.) Special Research Protections

Two federal laws, which may cover patient identifying information concurrently with the Part 2 regulations,¹¹⁴ protect certain researchers from being compelled to disclose any identifying characteristics about the individual research subjects.¹¹⁵ The first law allows the Secretary to authorize a Confidentiality Certificate for a person conducting research on mental health, including research on the use and effect of alcohol and psychoactive drugs; the second federal law allows the US Attorney General to authorize a Grant of Confidentiality for a person engaged in educational or research programs directly related to enforcement of laws under the Attorney General's jurisdiction concerning controlled substances. Researchers granted these confidentiality protections may not be compelled to disclose identifying information about their subjects in response to a court order entered under Part 2.

6.) Patient Rights

a.) Notice to Patients

At the time a patient is admitted or as soon as the patient is capable of rational communication (whichever is later), the program must inform the patient that federal law and regulations protect the confidentiality of substance abuse patient records¹¹⁶ and give the patient a written summary of those federal laws and regulations.¹¹⁷ The summary must include:

¹⁰⁸ 42 CFR § 2.35(a)(2).

¹⁰⁹ 42 CFR § 2.35(b)(1).

¹¹⁰ 42 CFR § 2.35(b)(2).

¹¹¹ 42 CFR § 2.35(b)(3).

¹¹² 42 CFR § 2.35(c).

¹¹³ 42 CFR § 2.35(d).

¹¹⁴ 42 CFR § 2.21(b).

¹¹⁵ 42 CFR § 2.21(a).

¹¹⁶ 42 CFR § 2.22(a)(1).

¹¹⁷ 42 CFR § 2.22(a)(2).

- A general description of the circumstances under which a program may acknowledge that an individual is present at a facility or disclose information identifying a patient as a substance abuser outside the program;¹¹⁸
- A statement that a program's violation of the federal law and regulations is a crime and that suspected violations may be reported to appropriate authorities;¹¹⁹
- A statement that information related to a patient's commission of a crime on program premises or against personnel of the program is not protected;¹²⁰
- A statement that reports of suspected child abuse and neglect made under state law are not protected;¹²¹
- A citation to the federal law and regulations.¹²²

The program may include information about state law and any program policy on the subject of confidentiality of substance abuse patient records.¹²³

b.) Patient Access

A program may give a patient access to his/her own records, including the opportunity to inspect and copy any records that the program maintains about the patient.¹²⁴ The program does not need to obtain the patient's written consent or other authorization in order to provide the patient with such access. Information obtained by the patient is subject to the restriction on use of that information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of him/her.¹²⁵

7.) Disclosures without Patient Consent

a.) Medical Emergencies

Patient identifying information may be disclosed to medical personnel who need the information to treat a condition posing an immediate threat to the health of any individual and requiring immediate medical intervention.¹²⁶ Patient identifying information may also be disclosed to medical personnel of the Food and Drug Administration (FDA) who 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, if the information disclosed will only be used to notify patients or their physicians of potential dangers.¹²⁷

Immediately following disclosure for such medical emergencies, the program must document the disclosure in the patient's records, including:

- The name of the personnel to whom disclosure was made and their affiliation with any health care facility;¹²⁸
- The name of the individual making the disclosure;¹²⁹
- The date and time of the disclosure;¹³⁰ and

¹¹⁸ 42 CFR § 2.22(b)(1).

¹¹⁹ 42 CFR § 2.22(b)(2).

¹²⁰ 42 CFR § 2.22(b)(3).

¹²¹ 42 CFR § 2.22(b)(4).

¹²² 42 CFR § 2.22(b)(5).

¹²³ 42 CFR § 2.22(c).

¹²⁴ 42 CFR § 2.23(a).

¹²⁵ 42 CFR § 2.23(b).

¹²⁶ 42 CFR § 2.51(a).

¹²⁷ 42 CFR § 2.51(b).

¹²⁸ 42 CFR § 2.51(c)(1).

¹²⁹ 42 CFR § 2.51(c)(2).

¹³⁰ 42 CFR § 2.51(c)(3).

- The nature of the emergency (or error, if the report was to FDA).¹³¹

b.) Research Activities

Patient identifying information may be disclosed to conduct scientific research if the program director determines that the recipient of the information:

- Is qualified to conduct the research;¹³²
- Has a research protocol under which s/he agrees to maintain the information in accordance with the security requirements discussed above in Section 2(c)(3)¹³³ and only re-disclose the information¹³⁴ back to the program that provided the information;¹³⁵ and
- Has provided a satisfactory written statement that a group of at least three individuals independent of the research project have reviewed the protocol and determined that the rights and welfare of patients will be adequately protected¹³⁶ and that the risks in disclosing information are outweighed by the potential benefits of the research.¹³⁷

A person conducting research may not identify any individual patient in any report of that research or otherwise disclose patient identities.¹³⁸

c.) Audit and Evaluation Activities

Patient identifying information may be disclosed to entities performing an audit or evaluation activity of the program, whether or not the records containing the patient identifying information will be copied or removed from program premises, only if the entity:

- Agrees in writing to comply with limitations on re-disclosure and use;¹³⁹ and
- Is performing the audit or evaluation on behalf of:
 - Any governmental agency that provides financial assistance to the program or is authorized by law to regulate its activities;¹⁴⁰ or
 - Any private entity that provides financial assistance to the program, is a third party payer covering patients in the program, or is a quality improvement organization performing a utilization or quality control review.¹⁴¹

If the patient records will not be copied or removed from program premises, the information may also be disclosed to any entity qualified to conduct the audit or evaluation activities, as determined by the program director.¹⁴² If the records will be copied or removed from program premises, the entity performing the audit or evaluation activity must agree in writing to:

- Maintain the patient identifying information in accordance with the security requirements discussed above in Section 2(c)(3) (or more stringent requirements);¹⁴³ and
- Destroy all patient identifying information upon completion of the audit or evaluation.¹⁴⁴

¹³¹ 42 CFR § 2.51(c)(4).

¹³² 42 CFR § 2.52(a)(1).

¹³³ 42 CFR § 2.52(a)(2)(i).

¹³⁴ 42 CFR § 2.52(a)(2)(ii).

¹³⁵ 42 CFR § 2.52(b).

¹³⁶ 42 CFR § 2.52(a)(3)(i).

¹³⁷ 42 CFR § 2.52(a)(3)(ii).

¹³⁸ 42 CFR § 2.52(b).

¹³⁹ 42 CFR § 2.53(a)(1), (b)(1)(iii).

¹⁴⁰ 42 CFR § 2.53(a)(1)(i), (b)(2)(i)..

¹⁴¹ 42 CFR § 2.53(a)(1)(ii), (b)(2)(ii).

¹⁴² 42 CFR § 2.53(a)(1)(iii)

¹⁴³ 42 CFR § 2.53(b)(1)(i).

¹⁴⁴ 42 CFR § 2.53(b)(1)(ii).

1. Limitations on Disclosure and Use

Unless it is for a Medicare or Medicaid audit or evaluation activity, patient identifying information may only be re-disclosed back to the program from which it was obtained and may only be used for an audit or evaluation purpose or to investigate or prosecute activities as authorized by an appropriate court order.¹⁴⁵

2. Medicare or Medicaid Audit and Evaluation Activities

A Medicare or Medicaid audit or evaluation is a civil or administrative investigation of the program by any agency overseeing the Medicare or Medicaid program and includes administrative enforcement of any remedy imposed as a result of the investigation against the program¹⁴⁶ or an employee of, or provider of medical services under, the program.¹⁴⁷ Any entity (including a quality improvement organization) that obtains patient identifying information during an audit or evaluation may disclose that information to an authorized person for purposes of a Medicare or Medicaid audit or evaluation.¹⁴⁸

d.) Certain Minors

If a minor patient or applicant's situation poses a substantial threat to the life or physical well-being of the minor or any other individual and the program director determines that the minor lacks the capacity for rational choice,¹⁴⁹ facts relevant to reducing such a threat may be disclosed to the minor's representative.¹⁵⁰

e.) Certain Incompetent Patients

If the program director determines that a patient (other than a minor or a person legally declared incompetent) suffers from a medical condition that prevents the patient from being able to take knowing or effective action on his/her own behalf, the program director may consent to disclosure of the patient's information for the sole purpose of obtaining payment for services from a third party payer.¹⁵¹

8.) Court Orders Authorizing Disclosure and Use

A court order may authorize a disclosure or use of patient information that would otherwise be prohibited by Part 2, but may not compel such disclosure.¹⁵² To compel disclosure of substance abuse records, a subpoena or similar legal mandate must also be issued. Entities holding substance abuse records that are subject to Part 2 may only disclose those records if an authorizing court order has been entered, even if a subpoena compelling their disclosure has been entered;¹⁵³ conversely, if an authorizing court order has been entered, the entity may refuse to disclose the records unless a valid subpoena is also entered.¹⁵⁴ If both an authorizing court order and a valid subpoena compelling disclosure have been entered, the entity authorized to disclose must do so, unless there is a valid legal defense other than the Part 2 confidentiality restrictions.

¹⁴⁵ 42 CFR § 2.53(d).

¹⁴⁶ 42 CFR § 2.53(c)(1).

¹⁴⁷ 42 CFR § 2.53(c)(2).

¹⁴⁸ 42 CFR § 2.53(c)(3).

¹⁴⁹ 42 CFR § 2.14(d)(1).

¹⁵⁰ 42 CFR § 2.14(d)(2).

¹⁵¹ 42 CFR § 2.14(a)(2).

¹⁵² 42 CFR § 2.61(a).

¹⁵³ 42 CFR § 2.61(b)(1).

¹⁵⁴ 42 CFR § 2.61(b)(2).

A court order may not authorize personnel who received patient identifying information without a patient's consent to conduct research, an audit, or evaluation to re-disclose that information or use it to conduct any criminal investigation or prosecution of a patient.¹⁵⁵ However, a court order may authorize disclosure and use of records to investigate or prosecute qualified personnel holding the records, as discussed below in Section 8(c).

A court order may authorize one of three things:

- Disclosure of confidential communications made by a patient to a program;
- Use of undercover agents and informants to criminally investigate a program's employees or agents; and
- Disclosure and use of records for one of three purposes.

a.) *Disclosure of Confidential Communications*

A court order may not authorize disclosure of confidential communications made by a patient to a program during diagnosis, treatment, or referral for treatment unless the disclosure is:

- Necessary to protect against a threat to life or of serious bodily injury;¹⁵⁶
- Necessary in connection with the investigation or prosecution of an extremely serious crime, such as one that directly threatens loss of life or serious bodily injury;¹⁵⁷ or
- In connection with litigation or an administrative proceeding where the patient offers testimony or other evidence related to the content of the confidential communications.¹⁵⁸

b.) *Use of Undercover Agents & Informants to Criminally Investigate a Program's Employees or Agents*

No program may knowingly employ, or enroll as a patient, any undercover agent or informant except as specifically authorized by a court order.¹⁵⁹

1. Application

Any law enforcement or prosecutorial agency that believes that employees or agents of a program are engaged in criminal misconduct may apply for a court order authorizing the placement of an undercover agent or informant in that program as an employee or patient.¹⁶⁰

2. Notice and Opportunity to Provide Evidence

Adequate notice and an opportunity to appear and provide evidence on the statutory and regulatory criteria for the issuance of the court order must be given to the program director, unless the application asserts a belief that the director:

- Is involved in the criminal activities to be investigated;¹⁶¹ or
- Will disclose the proposed placement of an agent or informant to the employees or agents who are suspected of criminal activities.¹⁶²

3. Criteria for the entry of the order

¹⁵⁵ 42 CFR § 2.62.

¹⁵⁶ 42 CFR § 2.63(a)(1). Note: "a threat to life or of serious bodily injury" includes verbal threats made against third parties, and "serious bodily injury" includes suspected child abuse or neglect.

¹⁵⁷ 42 CFR § 2.63(a)(2). Note: an extremely serious crime includes homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect.

¹⁵⁸ 42 CFR § 2.63(a)(3).

¹⁵⁹ 42 CFR § 2.17(a).

¹⁶⁰ 42 CFR § 2.67(a).

¹⁶¹ 42 CFR § 2.67(b)(1).

¹⁶² 42 CFR § 2.67(b)(2).

The court must determine that good cause exists by finding that:

- There is reason to believe that an employee or agent of the program is engaged in criminal activity;¹⁶³
- Other ways of obtaining evidence of this criminal activity are unavailable or would be ineffective;¹⁶⁴ and
- The public interest and need for the placement of an undercover agent or informant in the program outweigh the potential injury to patients of the program, physician-patient relationships, and treatment services.¹⁶⁵

4. Content of order

An order must:

- Specifically authorize the placement of an undercover agent or an informant;¹⁶⁶
- Limit the total period of the placement to six months;¹⁶⁷
- 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 program;¹⁶⁸ and
- Include measures to limit any potential disruption of the program by the placement and any potential for a real or apparent breach of patient confidentiality.¹⁶⁹

5. Other limitations

Information obtained by an undercover agent or informant (whether or not that agent or informant is placed in a program pursuant to an authorizing court order) may not be used to criminally investigate or prosecute any patient or as the basis for an application for an order to disclose patient records to criminally investigate or prosecute patients.¹⁷⁰

c.) Court Orders Authorizing Disclosure and Use of Records

A court order may authorize disclosure and/or use of patient records for one of three purposes:

- For noncriminal purposes;
- To criminally investigate or prosecute patients; and
- To investigate or prosecute a program or the entity holding the records

1. Who can apply for a court order authorizing disclosure and use of records?

- Disclosure for noncriminal purposes: any person with a legally recognized interest in the disclosure of patient records (other than for criminal investigation or prosecution).¹⁷¹
- Disclosure to criminally investigate or prosecute patients: an entity holding records or any person conducting criminal investigative or prosecutorial activities.¹⁷²
- Disclosure to investigate or prosecute a program or the entity holding the records: any agency with jurisdiction over a program's or record-holding entity's activities.¹⁷³

¹⁶³ 42 CFR § 2.67(c)(1).

¹⁶⁴ 42 CFR § 2.67(c)(2).

¹⁶⁵ 42 CFR § 2.67(c)(3).

¹⁶⁶ 42 CFR § 2.67(d)(1).

¹⁶⁷ 42 CFR § 2.67(d)(2).

¹⁶⁸ 42 CFR § 2.67(d)(3).

¹⁶⁹ 42 CFR § 2.67(d)(4).

¹⁷⁰ 42 CFR §§ 2.17(b), 2.67(e).

¹⁷¹ 42 CFR § 2.64(a).

¹⁷² 42 CFR § 2.65(a).

2. What are the requirements for the application for the court order?

The application for the order must use a fictitious name 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;¹⁷⁴
- The disclosure is for noncriminal purposes and the patient is the applicant;¹⁷⁵ or
- The disclosure is for noncriminal purposes or to investigate or prosecute a program or record-holder and the patient has given a valid written consent for the disclosure.¹⁷⁶

3. Is any notice or opportunity to provide evidence required?

Before a court order authorizing disclosure and/or use of patient records is granted, adequate notice of that application must be given to:

- The patient and the record-holder, if disclosure is for noncriminal purposes.¹⁷⁷
- The record-holder, if disclosure is to criminally investigate or prosecute a patient and the application is filed by a person performing a law enforcement function.¹⁷⁸

Notice must be made in a manner that will not disclose patient identifying information to others. No notice need be provided if the order is authorizing disclosure and/or use of patient records to investigate or prosecute a program or a record holder.¹⁷⁹

An opportunity to provide evidence on the statutory and regulatory criteria for the issuance of the court order must be given to:

- The patient and the record-holder, if the disclosure is for noncriminal purposes, either by filing a written response to the application or by appearing in person.¹⁸⁰
- The record-holder, if disclosure is to criminally investigate or prosecute a patient, by appearing in person.¹⁸¹
- The record-holder, the program, or any patient whose records are to be disclosed in order to seek revocation or amendment of an order authorizing disclosure to investigate or prosecute a program or a record holder.¹⁸²

In addition, if the disclosure is to criminally investigate or prosecute patients, the record-holder must be given an opportunity to be represented by counsel who is independent of counsel for an applicant who is performing a law enforcement function.¹⁸³

4. Are there any requirements for the conduct of hearings or the review of evidence?

For disclosures for noncriminal purposes or to criminally investigate or prosecute patients, any oral argument, review of evidence, or hearing on the application for the order must be held in a manner that ensures that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, or the entity holding the record.¹⁸⁴ This requirement does not apply if the

¹⁷³ 42 CFR § 2.66(a)(1).

¹⁷⁴ 42 CFR §§ 2.64(a), 2.65(a), 2.66(a)(2).

¹⁷⁵ 42 CFR § 2.66(a)(1).

¹⁷⁶ 42 CFR §§ 2.64(a), 2.65(a).

¹⁷⁷ 42 CFR § 2.64(b)(1).

¹⁷⁸ 42 CFR § 2.65(b)(1).

¹⁷⁹ 42 CFR § 2.66(b).

¹⁸⁰ 42 CFR § 2.64(b)(2).

¹⁸¹ 42 CFR § 2.65(b)(2).

¹⁸² 42 CFR § 2.66(b).

¹⁸³ 42 CFR § 2.65(b)(3).

¹⁸⁴ 42 CFR §§ 2.64(c), 2.65(c).

disclosure is for noncriminal purposes and the patient requests an open hearing in a manner that meets the requirements for written consent.¹⁸⁵ In either case, the judge may examine the patient records referred to in the application.¹⁸⁶

5. What are the criteria for the entry of an order?

For disclosures for any purpose, the court must find that the following criteria exist:

- Other ways of obtaining the information are unavailable or would be ineffective;¹⁸⁷ and
- The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship, and the treatment services.¹⁸⁸

In addition, for disclosures to criminally investigate or prosecute patients, the court must also find that:

- The crime involved is extremely serious (e.g., a crime that causes or directly threatens loss of life or serious bodily injury);¹⁸⁹
- There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution;¹⁹⁰
- If the applicant for the order is a person performing a law enforcement function, the record-holder was given the opportunity to be represented by independent counsel;¹⁹¹ and
- If the applicant for the order is a person performing a law enforcement function and the record-holder is a government entity, the record-holder was actually represented by independent counsel.¹⁹²

6. What must the content of the order include?

An order authorizing a disclosure or use of patient records for any purpose must:

- Limit disclosure to those parts of the patient's record that are essential to fulfill the objective of the order.¹⁹³
- Limit disclosure to those persons whose need for information is the basis for the order.¹⁹⁴

Orders authorizing disclosure for noncriminal purposes or to investigate or prosecute a program or a record holder must also include any measures necessary to limit disclosure for the protection of the patient, the physician-patient relationship, or the treatment services.¹⁹⁵ Orders authorizing disclosure to criminally investigate or prosecute patients must also:

- Limit the use of records by the law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution to the investigation and prosecution of extremely serious crime or suspected crime specified in the application;¹⁹⁶ and
- Include other measures necessary to limit disclosure and use to the fulfillment of only that which the court finds to be in the public's interest and need.¹⁹⁷

¹⁸⁵ 42 CFR § 2.64(c).

¹⁸⁶ 42 CFR §§ 2.64(c), 2.65(c).

¹⁸⁷ 42 CFR §§ 2.64(d)(1), 2.65(d)(3), 2.66(c).

¹⁸⁸ 42 CFR §§ 2.64(d)(2), 2.65(d)(4), 2.66(c).

¹⁸⁹ 42 CFR § 2.65(d)(1).

¹⁹⁰ 42 CFR § 2.65(d)(2).

¹⁹¹ 42 CFR § 2.65(d)(5)(i).

¹⁹² 42 CFR § 2.65(d)(5)(ii).

¹⁹³ 42 CFR §§ 2.64(e)(1), 2.65(e)(1), 2.66(c).

¹⁹⁴ 42 CFR §§ 2.64(e)(2), 2.65(e)(2), 2.66(c). Note: for disclosures to criminally investigate or prosecute a patient, those persons whose need for the information is the basis of the order are the law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution.

¹⁹⁵ 42 CFR §§ 2.64(e)(3), 2.66(c).

¹⁹⁶ 42 CFR § 2.65(e)(2).

7. Other Limitations

An order authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records must require the deletion of patient identifying information from any documents made available to the public.¹⁹⁷ No information obtained in accordance with such an order may be used to conduct any investigation or prosecution of a patient or be used as the basis for an application for an order authorizing disclosure and use of records to criminally investigate or prosecute patients.¹⁹⁹

¹⁹⁷ 42 CFR § 2.65(e)(3).

¹⁹⁸ 42 CFR § 2.66(d)(1).

¹⁹⁹ 42 CFR § 2.66(d)(2).