Confidentiality

AS IT APPLIES TO 42 CFR PART 2

Introduction

The purpose of this training is to provide basic information and overview of the complex and important area involving drug and alcohol abuse treatment records.

The Federal Statutes 42 CFR Part 2 will be discussed with emphasis on confidentiality and consent to disclosure information, and sanctions and penalties for unauthorized disclosure.

The Federal Statutes of HIPAA will also be discussed as to the role they play in Substance Abuse Treatment Records and how they apply to the statutes of 42 CFR Part 2.

Applicability

Who is covered?

Drug/alcohol treatment and prevention programs that are Federally assisted must follow 42 C.F.R. Part 2

Applies to records in the possession of "other lawful holders of patient identifying information" (e.g., individuals or entities who receive such records pursuant to a Part 2-compliant patient consent).

Lawful Holder

A “lawful holder” of patient identifying Part 2 information is an individual or entity who has received such information as the result of a Part 2 compliant patient consent (along with a notice of prohibition on re-disclosure) or as a result of one of Part 2’s limited exceptions to the consent requirements.

Program 1st Definition

What is a "program"? Three definitions…

First definition

Individual or entity, other than general medical facility, that holds itself out as providing, and does provide, drug/alcohol diagnosis, treatment, or referral for treatment…

Program 2nd Definition

What is a "program"? Three definitions (continued)

Second definition

An identified unit within a general medical facility that holds itself out as providing, and does provide, drug/alcohol diagnosis, treatment, or referral for treatment…

Further, if the provisions of such services are identified as a primary function of medical personnel or the general staff in the general medical facilities, they are considered a "Program," and are therefore subject to the rules and regulations in Part 2.

Program 3rd Definition

What is a "program"? Three definitions (continued)

Third Definition

Medical personnel or other staff, in a general medical care facility, whose primary function is the provision of drug/alcohol diagnosis, treatment, or referral for treatment, and who are identified as such.

SAMHSA FAQ

What does "**holds itself out**" mean?

Law does not define

SAMHSA has established the definition of "holds itself out "and is defined as any activity that would lead one to reasonably conclude that the individual or entity provides substance use disorder diagnosis, treatment, or referral for treatment including but not limited to:

- Authorization by the state or federal government (e.g. licensed, certified, registered) to provide, and provides, such services,
- Advertisements, notices, or statements relative to such services, or
- Consultation activities relative to such services

Federally Assisted

When is a program "federally assisted"?

Receives Federal funds in any form (even if not used for drug/alcohol services), or

Is authorized, licensed, certified, registered by the Federal government, such as—

Assisted by IRS by grant of tax-exempt status

Has DEA registration to dispense controlled substances to treat drug/alcohol abuse

Is authorized to provide methadone treatment

Is certified to receive Medicaid or Medicare reimbursement

Who is a Patient

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 program.

Patient Rights

Patients must be given written summary of confidentiality provisions and notice that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records.

This is separate from the HIPAA Notice of Privacy Practices

Patient Identifying Information

Patient identifying information means the name, address, social security number, fingerprints, photographs, or other 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.

Neither written or unrecorded Patient information, such as verbal statements, may be disclosed.

Patient Access to Records

No consent nor authorization required to access

Also subject to restriction on use 2.23(b)

The General Rule Prohibiting Disclosure

Except under certain specified conditions, the regulations prohibit the disclosure of records or other information concerning any Patient in a federally assisted alcohol or drug program § § 2.13 (b), 2.20.

This prohibition on unauthorized disclosure applies whether or not the person seeking information already has the information, has other means of obtaining it, enjoys official status, has obtained a subpoena or warrant, or is authorized by state law. § § 2.13 (b), 2.20.

If a program receives a request for a disclosure of an individuals records that is not permitted by the regulations, it must refuse to make the disclosure, and must be sure to do so in a way that does not reveal that the individual has ever been diagnosed or treated for an alcohol or drug problem.

Nine Exceptions to the Non Disclosure Rule

1. No Patient identifying information
2. Internal Communications
3. Proper Consent
4. QSOA
5. Crime on Program Premises or against program personnel anywhere
6. Research/Audit
7. Court Order
8. Medical Emergency
9. Reporting suspected child abuse or neglect

No Patient Identifying information

The Federal regulations permit programs to disclose information about a Patient if the program reveals no Patient-identifying information. Thus, a program may disclose information about a Patient if that information does not identify the Patient as a substance abuser or does not verify anyone else's identification of the Patient as a substance abuser.

Internal Communications

Program staff may share information about a Patient with other staff when necessary to provide a treatment related service.

This information should be given to other staff members on a "need to know basis".

For example: A Patient informs his counselor that he has a liver disease. The counselor can inform the supervisor, the nurse and the social worker but not the receptionist or janitor.

A Patient informs her counselor that she has had suicidal thoughts, the counselor can then relate this information to the supervisor, social worker, nurse and even the janitor and receptionist, so that all staff can properly monitor the Patient.

Proper Format for ROI's

A proper consent form must be in writing and must contain each of the items specified in § 2.31:

The name or general designation of the program(s) making the disclosure;

The name of the individual or organization that will receive the disclosure;

The name of the Patient who is the subject of the disclosure;

The purpose or need for the disclosure

How much and what kind of information will be disclosed

A statement that the Patient may revoke the consent at any time, except to the extent that the program has already acted in reliance on it;

The date, event or condition upon which the consent expires if not previously revoked;

The signature of the Patient (and/or other authorized person)

The date on which the consent is signed.

A general medical release form, or any consent form that does not contain all of the elements listed above, is <u>not</u> acceptable!

Revoking Consent

Most disclosures are permissible if a Patient has signed a valid consent form which has not been expired or revoked by the Patient. §2.13* if authorized by the Patient's valid consent, a disclosure is permitted even if it may not be in the Patients best interests. The regulations set up the Patient as the final arbiter of disclosures in most situations.

If a Patient puts in writing or verbalizes that he or she wants to revoke consent you must do the following two things:

1. Log the revocation in the progress notes of the chart;

2. Make a notation on the consent and place in the Patients chart.

Criminal Justice System Referrals

As for the revocability of the consent, the regulations provide that the consent form can state that it cannot be revoked until a certain specified date or condition occurs. The regulations permit the CJS consent form to be irrevocable so that an individual who has agreed to enter treatment in lieu of prosecution or punishment cannot then prevent the court or probation, parole or other agency from monitoring his or her progress.

CJS (cont.)

Note that although a CJS consent may be made irrevocable for a specified period of time, its irrevocability must end no later than the final disposition of the criminal proceeding. Thereafter, the Patient may freely revoke consent. § 2.35(c).

Prohibition on Re-disclosure

SAMHSA clarifies the prohibition on re-disclosure only applies to information that would identify, either directly or indirectly, a person as having been diagnosed, treated or referred for treatment for a SUD. Essentially, when the patient consents to having information released to a particular individual, the individual receiving the information may not re-disclose it to a third party.

Prohibition on Re-disclosure (cont.)

For example, if a person receives substance use treatment from a Part 2 program, and receives treatment for another condition such as heart murmurs, the patient's record would include information unrelated to SUD (i.e., heart murmurs). Section K does not prohibit re-disclosure of the information related to the heart murmurs so long as it does not include information that would identify the patient as having or having had a SUD.

Prohibition on Redisclosure Statement

1) 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 information in this record that identifies 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 unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed 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 (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65. or

2) 42 CFR part 2 prohibits unauthorized disclosure of these records.

Minimum Necessary

Patient identifying information may only be used or disclosed as permitted by the regulations and must be limited to that information which is necessary to carry out the purpose of the disclosure.

In addition, disclosures made pursuant to a court order must be limited to the criminal or non-criminal purposes stated in the court order and the regulations.

Accounting of Disclosures

Permits the patient to obtain a list of entities that received their information in the previous two years under a general designation consent.

Patient requests must be made in writing.

The response would need to include the name of the recipient entity, the date of the disclosure, and a brief description of the information disclosed.

The entity must respond in 30 or fewer days following the receipt of the written request.

Qualified Service Organization Agreement

If a program routinely needs to share certain information with an outside agency that provides services to the program, it can enter into a QSOA.

A *QSOA* is a written agreement between a program and a person providing services to the program in which that person (1) acknowledges that in receiving, storing, processing, or otherwise dealing with any Patient records from the program, he or she is fully bound by [the Federal confidentiality] regulations; and (2) promises that, if necessary, he or she will resist in judicial proceedings any efforts to obtain access to Patient records except as permitted by these regulations (§§2.11, 2.12(c)(4)).

Qualified Service Organization (cont.)

A “Qualified Service Organization” (QSO) now includes entities that provide population health management to a Part 2 program, meaning relevant patient information may be shared with third-party vendors supporting population health initiatives without patient consent

Crimes on Premises

Alcohol and drug programs may disclose Patient identifying information to the police or other law enforcement agencies when a Patient commits or threatens to commit a crime on program premises (against anyone) or against program personnel anywhere.

The program can make this disclosure of patient identifying information to police or other law enforcement officers but not to anyone else.

The police report must be limited to the:

1. Particulars of the crime

2. Patients name

3. Patients address; and

4. Patients last known whereabouts

Research

Programs may disclose patient identifying information to qualified researchers if they follow the protocols required by the federal regulations.

These protocols include pledging not to re-disclose patient identifying information except back to the program.

For more information on disclosures to researchers see § 2.52 of the regulations.

Subpoenas/Court Orders

A subpoena alone is not sufficient to release information - a court order is also required - must be issued by judge in accordance with specific procedures and criteria

Requirements of Court Orders

The requirements under the federal regulations for a court order are as follows:

1. Notice to Patient and program.
2. Opportunity to be heard.
3. Fictitious name.
4. Confidential proceedings; and
5. Good cause

Search & Arrest Warrants

Neither a search warrant or an arrest warrant without a court order obtained in accordance with 42 CFR Part 2 is sufficient to authorize an alcohol or drug program to disclose any Patient identifying information.

When a police officer or other law enforcement officer arrives at the program with a search warrant or arrest warrant program personnel should:

Produce a copy of the federal regulations

Explain that the program may not cooperate without a valid court order obtained in accordance with 42 CFR Part 2.

If at all possible seek an attorney's assistance in the matter.

Contact the commanding officer and prosecuting attorney and explain the federal regulations.

Do not forcibly resist a police officers attempt to enter the program

Medical Emergencies

An alcohol or drug program may disclose any necessary information:

To medical personnel only (not family members)

Who need the information in order to treat a condition which poses an immediate threat

To the health of any individual, and

Which requires immediate medical intervention.

No consent is required

Medical personnel may re-disclose patient identifying information to family members and others without patient consent.

Medical Emergency (cont.)

Programs must document every disclosure made in a medical emergency by recording.

Name of individual who made the disclosure

Name and affiliation of the recipient of the disclosure

Date and time of the disclosure, and

Nature of the emergency.

Medical Emergency (cont.)

"Medical Emergency" definition in §2.51 now gives providers more discretion to define the existence of a "bona fide medical emergency."

Patient identifying information may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency, in which the patient's prior informed consent cannot be obtained.

Child Abuse/Neglect Reporting

Specific exception allows reporting of child abuse/neglect

Restrictions on disclosure and use continue to apply to the original alcohol and drug abuse patient records maintained by the program including their disclosure or use for criminal or civil proceedings which may arise out of the report

Public Health Authorities/Disease Reporting

No specific exemption for reporting - need consent, court order, or can report if done anonymously, state law will dictate mandatory reporting.

Can disclose to FDA if error in manufacturing e.g., labeling or sale of drug used in treatment - exclusive purpose notifying Patients and their physicians of potential dangers.

Security

The Final Rule creates more detailed requirements for protecting the security of records.

Specifically, Part 2 now requires that both Part 2 programs and lawful holders have established formal policies and procedures for the security of both paper and electronic records.

The new security requirements align more closely with those of the HIPAA Security Rule.

Enforcement, Compliance and Penalties

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

(b) The report of any violation of the regulations in this part by an opioid treatment program may be directed to the United States Attorney for the judicial district in which the violation occurs as well as to the Substance Abuse and Mental Health Services Administration (SAMHSA) office responsible for opioid treatment program oversight

Enforcement, Compliance and Penalties

Under 42 U.S.C. 290dd–2(f), any *person* who violates any provision of this section or any regulation issued pursuant to this section shall be fined in accordance with Title 18 of the U.S. Code

Recent Regulatory Changes

“To Whom” Consent Requirements (§2.31):

The patient must include certain language in the “To Whom” section of the consent form in order for the general disclosure to be valid. SAMHSA also clarified in the new rule that if a patient uses a general designation listing “my treating providers” without specifying whether the designated providers are “past, current, and/or future,” it should be presumed the patient intended to only designate “current” treating providers.

To Whom (cont.)

Further, if the program designated is part of a general medical facility, the modifications to Part 2 permit the patient to designate the entire entity so long as a list of information to be disclosed is included on the consent form. For example, a patient may provide general disclosure to an entity that does not have a treating provider relationship, such as a Health Information Exchange (HIE) in order to permit disclosure to those participants in the HIE that do have a treating provider relationship with the patient.

Amount and Kind Consent Requirements (§2.31):

The “Amount and Kind” of information to be disclosed and the purpose of the disclosure was revised to require more specificity. The revision requires the SUD information disclosed be explicitly described. This is so patients know exactly what they are signing, and so patients may consent only to the disclosure of subsets of information.

Amount and Kind (cont.)

These include “diagnostic information, medications and dosages, lab tests, allergies, substance use history summaries, trauma history summary, elements of a medical record such as clinical notes and discharge summary, employment information, living situation and social supports, and claims/encounter data.” For example, “all of my records” is an insufficient description, while “all of my substance use disorder records” is sufficient.

Disclosure Tracking §2.13(d):

Because the final rule permits patients to include a general disclosure designation (described above), revisions require Part 2 programs to provide to patients, upon request, a list of entities to whom their information has been disclosed.

The request must be in writing (paper or electronic), and is limited to disclosures within the past two years. Entity names designated on the request must respond within 30 days with a brief description of each disclosure. There is no given timeframe for compliance with this rule; however, entities must be able to provide a list of disclosures upon request in order to have the option of disclosing information outlined in the general designation on a consent form.

Form of Documents (§2.16)

42 CFR Part 2 now applies to both paper and electronic documentation. The provisions include formal policies and procedures addressing security, including electronic file destruction of associated media. A program subject to 42 CFR Part 2 must have established formal policies and procedures for the security of both electronic and paper records.

Form of Documents (cont.)

Generally, the text and preamble of 42 CFR Part 2 make it clear the responsibility of explaining patients' rights falls on the treatment program. Therefore, programs should be advised to review and/or make changes to the following: consent documents, prohibition on re-disclosure statements, QSO categorization, security policies and procedures (including those regarding permitted disclosures), and general contractual documentation.