CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT INFORMATION

myLearningPointe™

Slide 1.1 Welcome

Welcome to today's training. Today's topic is Confidentiality of Substance Use Disorder Patient Information, a part of the myLearningPointe course library. This course is relevant to persons providing health services to Substance Use Disorder consumers. Following the guidance of SAMHSA in the final rule published January of 2017, this course does not address Prescription Drug Monitoring Programs or other state regulations.

Slide 1.2 Course Instructions

When viewing this course, you will need to click the Next button on the bottom right of this course player at the end of each slide. To view the last slide watched, click Previous. The Pause and Play buttons are on the bottom to the left of the green Progress bar. The Progress bar also performs the fast forward and rewind functions. Click in the Progress bar to move back or forward in the current slide. You can also navigate the course using the menu outline on the left. You might find other information relevant to the course in the Resources tab located at the top. When viewing the final slide of this course, please let it play to its end.

Slide 1.3 Introduction

This course focuses on the confidentiality of alcohol and drug patient information. While all patients are afforded protection of their information under both the HIPAA and HITECH Acts, patients in alcohol and drug treatment programs are given additional protections under the Code of Federal Regulations Title 42, Chapter I Public Health Service, Department of Health and Human Services, Subchapter A General Provisions, Part 2 Confidentiality of Substance Use Disorder Patient Records. This is referred to as 42 CFR Part 2.

The Department of Health and Human Services (HHS) issued a final rule on January 16, 2017 making some modifications to 42 CFR Part 2. This final rule went into effect on March 21, 2017. This course reflects the modifications made by this final rule.

Persons who receive treatment for mental health and substance use disorders may be referred to as clients, participants, or some other term rather than as patients. In this course we use the term patient for consistency with the language in the laws.

As you progress through the slides you will see this marker, indicating the final rule for 42 CFR Part 2. Click the symbol to view changes made by the final rule published January 16, 2017. This information is presented as text only and is optional.

Slide 1.4 Course Objectives

By the time you complete this course, you should be able to:

- Name the primary acts which protect patient confidentiality
- Describe specific protections for persons seeking treatment for substance use disorders
- List the disclosures permissible with and without patient consent

Slide 2.1 Confidentiality of Patient Information

Confidentiality of Patient Information

Slide 2.2 Primary Federal Laws

There are three federal laws which specifically address confidentiality of patient information:

- HIPAA – the Health Insurance Portability and Accountability Act of 1996,
- HITECH – the Health Information Technology for Economic and Clinical Health Act of 2009, and
- 42 CFR Part 2 – the Drug Abuse Office and Treatment Act of 1972.

Each of these laws has been modified since it was originally enacted. The Department of Health and Human Services has made modifications to these rules due to a number of changes in the healthcare industry, including the use of electronic records for patient information, the ability of health information systems to exchange information, and the integration of all aspects of health care for both physical and mental health.

Clinicians working in the fields of mental health and substance use treatment walk a particularly thin line when ensuring their patients are receiving appropriate care for their mental health disorders and their physical health disorders. If you are unsure of your obligations in maintaining the confidentiality of your patients, consult your supervisor, compliance director, facility director, or legal team for specific guidance.

Slide 2.3 42 CFR Part 2 History

The Drug Abuse Office and Treatment Act of 1972 was enacted to address the increasing drug use in the United States. The stigma of seeking treatment for drug or alcohol use was at that time, and still is, an impediment for many persons who may need treatment. Ensuring confidentiality of those seeking treatment for substance use is paramount to encouraging persons to seek treatment.

Prior to the final rule issued in January 2017, the last substantive amendments to 42 CFR Part 2 were made in 1987. As noted on the previous slide, technology and the integration of all aspects of healthcare necessitated some changes to the laws.

Slide 2.4 HIPAA History

The primary impetus behind HIPAA in 1996 was to give consumers a way to maintain their health insurance coverage. The legislation also included provisions in the Administrative Simplifications section of the Act which address electronic transmission of administrative and financial transactions; unique health identifiers for individuals, employers, health plans, and health care providers; and privacy and security standards protecting the confidentiality of an individual's health information. In 2017 most people associate HIPAA solely with the regulations concerning patient confidentiality.

In January 2013, a final rule amending HIPPA was issued by HHS. These modifications were enacted due to statutory amendments made by HITECH and by the Genetic Information Nondiscrimination Act (GINA) of 2008.

Slide 2.5 HITECH History

The HITECH Act was created to stimulate adoption of electronic health records and increase the use of technology in health care, as part of the American Recovery and Reinvestment Act of 2009. HITECH provided financial incentives for Eligible Providers installing and using technology in a meaningful way, referred to as meaningful use. Meaningful use was implemented by providers in three stages.

A final rule was issued in October 2015 with an effective date of December 2015 by CMS (the Centers for Medicare and Medicaid Services, a division of the Department of Health and Human Services). This final rule defined requirements for Stage 3 of meaningful use and the timelines and reporting periods.

Slide 2.6 HIPAA Privacy Regulations

HIPAA requires individuals and organizations to prevent inappropriate use and disclosure of individuals' health information, and requires organizations that use health information to protect that information and the systems which store, transmit, and process it.

Protected Health Information (PHI) is defined by the HIPAA Act as individually identifiable health information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. In plain English, this is any health information no matter what its form – electronic, paper, oral, etc. This even includes health information transmitted in a casual conversation.

Individually identifiable health information is defined as a subset of health information which includes an individual's demographic information, as well as information created or received by a healthcare provider, health plan, employer, etc. that relates to the past, present, or future physical or mental health or condition of an individual. This information includes the provision of health care to an individual or payment for the provision of healthcare to an individual. In plain English, any information which could identify an individual or could reasonably be believed to identify an individual is considered individually identifiable health information.

Slide 2.7 Examples of Protected Health Information

Shown here is a partial list of categories which could identify an individual:

- Name
- Geographical subdivision smaller than a state, except for the first three digits of a Zip Code
- All dates, except for the year including birth/death dates, admission/discharge dates, all years for those over 89 (can be grouped into a category “over 90”)
- Phone or fax number
- Email address
- Social Security Number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate/license number
- Vehicle identifiers and serial numbers (including license plates)
- Device identifiers and serial numbers
- Web URL
- IP address
- Biometric identifier (for example, a fingerprint)
- Full-face photograph and any comparable image
- It also includes identifiable information of relatives, household members, and employers.

Individually identifiable health information would also include information created or received by a healthcare provider, health plan, employer, and others that relates to the past, present, or future physical or mental health or condition of an individual.

Slide 2.8 Summary

The confidentiality of patient information regarding physical health, mental health, or treatment for substance use disorder is not only an obligation of clinicians and other staff of healthcare facilities, but is also a legal requirement. Federal laws that regulate the confidentiality of protected health information apply to persons and organizations in the United States. Some states have additional requirements. You should also become familiar with any specific rules and regulations for your state.

The fundamental point is only persons who have a valid need to know should have access to protected health information in all healthcare situations. You must protect that information from being disseminated inappropriately whether it is written on paper, stored and/or transmitted electronically, or orally communicated to others who have a valid reason to know.

42 CFR Part 2 places additional restrictions beyond those required by HIPAA on those who work with persons receiving treatment for drug and alcohol use disorder. The subsequent slides in this presentation cover in detail the requirements of the part 2 regulations.

Slide 2.9 Activity

These three acts set requirements for confidentiality of patient information. Which is specific to those receiving treatment for substance use disorder?

HIPAA – the Health Insurance Portability and Accountability Act of 1996

HITECH – the Health Information Technology for Economic and Clinical Health Act of 2009

42 CFR Part 2 – the Drug Abuse Office and Treatment Act of 1972

Slide 2.10 Activity

Protected Health Information (PHI) includes the name of a patient's father.

True

False

Slide 3.1 42 CFR Part 2 Subparts A and B Introduction and General Provisions

42 CFR Part 2 Subpart A Introduction and Subpart B General Provisions

Slide 3.2 Purpose

The purpose of the Confidentiality of Substance Use Disorder Patient Records rule is to impose restrictions on information which may be released, specify the processes for releasing information, provide definitions of key terms, and apply the restrictions to the appropriate programs.

The regulations are intended to make sure that persons who receive treatment for substance disorders are not made more vulnerable because of their participation in the program. Vulnerability is understood to mean that the person is discriminated against or stigmatized because they are receiving or have received treatment for their disorder.

Final Rule changes

- *Old §2.1 Confidentiality of drug abuse patient records and §2.2 Confidentiality of alcohol abuse patient records were combined into the new §2.1 Confidentiality of substance use disorder patient records. Remaining sections were renumbered.*
- *No changes for newly numbered §2.2 Purpose and effect*

Slide 3.3 Penalties and Violations

Criminal penalties are applicable to both individuals and organizations who violate 42 CFR Part 2. Violations are reported to the United States Attorney for the judicial district where the violation occurs. If the violation occurs in an organization providing an opioid treatment program it may also be reported to the Substance Abuse and Mental Health Services Administration (SAMHSA) which oversees the opioid treatment programs. Opioid treatment programs were referred to as methadone programs.

Final Rule changes

- *No changes for §2.3 Criminal penalties for violations*
- *§2.4 Reports of violations. New §2.4(b) replaces methadone programs with opioid treatment programs. It also changes reporting of violations from the Food and Drug Administration (FDA) to the Substance Abuse and Mental Health Administration (SAMHSA), which now oversees opioid treatment programs.*

Slide 3.4 Definitions

Key definitions for terms used in 42 CFR Part 2 are found in section 2.11. Rather than review the definitions in this course, a list of definitions can be found under the Resources tab for this course. This definition document notes if the definition was changed or added based on the final rule and lists the definitions which were replaced or deleted. As needed in subsequent sections, some definitions will be given on later slides in this course.

Final Rule changes

- *§2.11 as noted on this slide, most definitions in the older version were relocated to this section. Some definitions were changed or updated to reflect current terminology. Some definitions were replaced or deleted. A list of definitions is under the Resources tab of this course.*

Slide 3.5 Applicability

The law restricts disclosure of any information, whether it is recorded or not, "which 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 information by another person; and is drug abuse information obtained by a federally assisted drug abuse program…, or is alcohol abuse information obtained by a federally assisted alcohol abuse program…; or … is maintained by a part 2 program … as part of an ongoing treatment episode for the purpose of treating a substance use disorder, making a diagnosis for that treatment, or making a referral for that treatment."

Federally assisted means a direct program of a department or agency of the United States; a program that is contracted by a department or agency of the United States; or a program that is licensed, certified, registered, or run under authorization granted by a department or agency of the United States. These federally assisted programs include:

- Participants in the Medicare program,
- Programs authorized to conduct maintenance or withdrawal treatment,
- Programs registered to dispense a substance under the Controlled Substances Act as part of the treatment program,
- Programs supported by funds provided by any department or agency of the United States, and
- Programs assisted by the IRS (Internal Revenue Service) through the allowance of income tax deductions for contributions to the program.

These programs are referred to as "Part 2 programs" in the regulations.

Final Rule changes

- *§2.12 Applicability. The terms "general medical facility" and "general care medical facility" are combined as "general medical facility." It also revises (d)(2)(i)(C) so that restrictions on disclosures also apply to individuals or entities who receive patient records from other lawful holders of patient identifying information.*

Slide 3.6 Exceptions to General Restrictions

The regulations do not apply to information on substance use disorder patients under the circumstances described here. Click each circle to view an exception.

1. Information maintained by the Department of Veterans Affairs in their provision of hospital care, nursing home care, domiciliary care, and medical services.
2. Information obtained for members of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice for interchange of information within the Armed Forces and interchange of information between the Armed Forces and the Department of Veterans Affairs who are providing health care to veterans.
3. Communication of information within a part 2 program or between a part 2 program and an entity having direct administrative control over the program. The restrictions do, however, apply to persons receiving the information, which includes third-party payers.
4. Communication between a part 2 program and a qualified service organization of information needed by the qualified service organization to provide services.
5. Communications to law enforcement agencies or officials when a patient has committed a crime on the premises of a part 2 program or against personnel of a part 2 program. Information in this instance is limited to the circumstances of the incident, including the patient status, name and address, and the last know whereabouts of the individual committing or threatening to commit a crime.
6. Communications made under state law for reporting incidents of suspected child abuse and neglect to appropriate state or local authorities. This exception does not apply to the original substance use disorder records of the patient for disclosure or use in civil or criminal proceedings which result from the report of child abuse or neglect.

Slide 3.7 Created by Part 2 Program

The regulations apply to any information about patients, including referral and intake about patients receiving diagnosis, treatment, or referral for treatment for a substance use disorder, if that information was created by a part 2 program. Put another way, this is any information gathered by a program which receives any federal assistance. Coverage includes, but is not limited to, treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as providing substance use disorder diagnosis, treatment, or referral for treatment.

An example of an exception to this regulation is 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.

Slide 3.8 Exception Example

The regulation gives the following example as an exception.

“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… 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…”

Slide 3.9 Acknowledging the Presence of Patients

If a facility is publically identified as a place where only substance use disorder treatment or referral for treatment is made, a patient's presence may only be acknowledged with consent of the patient or if an authorizing court order is in place. If a patient is in a health care facility or part of a facility which is not identified as only providing substance use disorder diagnosis, treatment, or referral for treatment, the facility may disclose the presence of the patient, provided that they do not disclose the patient is present for diagnosis, treatment, or referral for treatment of the substance use disorder.

If a patient has consented to disclosure of their presence, the patient may request and must be provided a list of entities to which their information was released. That list must be provided in writing and is limited to disclosures made within the past two years. The facility must respond to the patient within 30 days of the request and provide for each disclosure who the information was disclosed to, a brief description of the information disclosed, and the date of the disclosure.

Final Rule changes

- *§2.13 a patient must be provided a list in writing of who their information has been disclosed to within 30 days. This is limited to disclosures made within the past two years. This applies when a general designation has been made in the "To Whom" section of their consent form. Written may be either paper or electronic. SAMHSA further clarifies that a general designation may not be used on a form until an entity has the ability to provide the written list. Included in this provision is any entity who acted as an intermediary in disclosing the information.*

Slide 3.10 Minor Patients

Disclosure of information relating to a minor is dependent upon state law. There are three considerations for minor patients. Click each number.

1. State law not requiring parental consent to treatment. If the minor may act alone under state law, the minor's consent must be given before information is given. This includes information to the parent or guardian for the purpose of obtaining financial reimbursement. A part 2 program may refuse to provide treatment until the minor consents to the disclosure necessary to obtain reimbursement.
2. State law requires parental consent to treatment. The minor's application for treatment may be communicated to the parent, guardian, or other individual authorized under state law if the minor has given consent or if the minor lacks the capacity to make a rational choice regarding consent as judged by the part 2 program director.
3. Minor applicant for services lacks capacity for rational choice. The parent, guardian, or other individual authorized under state law may be informed of facts relevant to reducing a substantial threat to the life or physical well-being of the minor applicant. This lack of capacity is because of extreme youth or mental or physical condition that the minor lacks the ability to make a rational decision on whether to consent and there is a substantial threat to the life or physical well-being of the minor or any other individual which may be reduced by communicating relevant facts to the parent, guardian, or other individual authorized under state law.

Final Rule changes

- *No changes were made to this section.*

Slide 3.11 Incompetent and Deceased Patients

The provisions in §2.15 do not apply to minors.

If a patient has been adjudicated as lacking the capacity to handle their own affairs, consent may be given by the guardian or other individual authorized under state law to act on the patient's behalf. If the patient has not been adjudicated as incompetent, but for a period suffers from a medical condition that prevents knowing or effective action on their own behalf, the part 2 program director may consent to disclosure on behalf of the patient solely to obtain payment for services from a third-party payer.

In the case of a deceased patient, identifying information may be released to vital statistics relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death. Other information identifying a patient as having a substance use disorder may only be released with written consent of an executor, administrator, or other personal representative appointed under applicable state law.

Final Rule changes

- *No changes were made to this section*

Slide 3.12 Undercover Agents and Informants

Unless authorized by a court order, not part 2 program may knowingly employ or enroll as a patient any undercover agent or informant. If a court order exists, no information obtained by the agent or informant placed in a part 2 program may be used to criminally investigate or prosecute any patient.

Final Rule changes

- *No changes were made to this section*

Slide 3.13 Identification Cards

A part 2 program may require a patient to carry in their immediate possession a card or other identification object identifying the patient as participating in a substance use disorder program while on the premises, but may not require that the identification be carried while away from the premises of the part 2 program.

Final Rule changes

- *No changes were made to this section*

Slide 3.14 Relationship to Other Laws

While state laws may be more restrictive than 42 CFR Part 2, no state law may be more permissive than 42 CFR Part 2 regarding patient identifying information.

The Secretary of Health and Human Services and the United States Attorney General have the power to regulate information used by researchers. If you are conducting research, you should clarify with your legal department what is and is not permissible.

Final Rule changes

- *No changes were made to this section*

Slide 3.15 Notice to Patients of Federal Confidentiality Requirements

When a patient is admitted to a part 2 program, the patient or their parent, guardian, or authorized individual must be informed of federal law and regulations protecting the confidentiality of substance use disorder patient records, and this summary must be provided in writing. Click each number to view what the written summary must include:

1. A general description of the limited circumstances under which a part 2 program provider may acknowledge the patient is present and what information may be disclosed.
2. A statement that violation of the federal law and regulations is a crime and where violations of the law and regulations may be reported.
3. A statement that information related to a patient's commission of a crime on the premises of the part 2 program or against personnel of the part 2 program is not a violation of the federal law.
4. A statement that reports of suspected child abuse or neglect are not a violation of the federal law.
5. A citation to the federal law and regulations.

The summary many also include any applicable state laws or any portion of the part 2 program's policies that are not inconsistent with the federal laws.

Final Rule changes

- *§2.22 Notice to patients of federal confidentiality requirements. Written now includes both paper and electronic formats.*

Slide 3.16 Patient Access

Patients are permitted access to their own records, including the opportunity to inspect and copy any records the part 2 program maintains about the patient. Written consent by the patient is not required when providing this information to the patient. Information the patient obtains may not be used to initiate or substantiate any criminal investigation of the patient.

Final Rule changes

- *No changes were made to this section*

Slide 3.17 Activity

Which of these are exceptions to the confidentiality of alcohol and drug patient information under certain conditions?

- Communication between a part 2 program and a qualified service organization
- Communication of information within a part 2 program or between a part 2 program and an entity having direct administrative control over the program
- Communications made under state law reporting incidents of suspected child abuse and neglect to appropriate state or local authorities
- Communications to law enforcement agencies or officials when a patient has committed a crime on the premises of a part 2 program or against personnel of a part 2 program
- Information maintained by the Department of Veterans Affairs
- Information obtained for members of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice.

Slide 3.18 Activity

You work for a part 2 program, and a local well-known community member has entered your program. A phone call is directed to you from the grandparent of the patient requesting information regarding when family is allowed to visit. You are allowed to tell the family member when the patient may receive visitors.

- True
- False

Slide 3.19 Activity

Parents always have the right to access their minor child's records.

- True
- False

Slide 3.20 Activity

Violations of 42 CFR Part 2 are reported to: (Select 2)

- The United States Attorney for the judicial district where the violation occurs
- Substance Abuse and Mental Health Services Administration (SAMHSA) – if an opioid treatment program
- Food and Drug Administration (FDA) – if an opioid treatment program

Slide 4.1 Subparts C, D, and E – Disclosures

Subparts C, D, and E – Disclosures

Slide 4.2 Quick View

Subpart C defines disclosures of information with patient consent, including what is required on the consent form. Subpart D defines disclosing patient information without patient consent, specifically in medical emergencies, for research, or for audit and evaluation. Finally, Subpart E defines the specifics for a court authorization releasing information, as was mentioned in the prior section.

Slide 4.3 Consent Requirements

While no specific form is required for patient consent, section 2.31 lists the required elements of the consent form. The consent form may be either paper or electronic. The form must include:

1. The name of the patient.
2. The specific name or general designation of the part 2 program, entity, or individual permitted to make the disclosure.
3. How much and what kind of information is to be disclosed, including an explicit description of the substance use disorder information that may be disclosed.
4. The name of the individual, individuals, entity, or entities to whom a disclosure is to be made
5. The purpose of the disclosure.
6. A statement that the consent is subject to revocation at any time except to the extent that the part 2 program or other lawful holder of patient identifying information that is permitted to make the disclosure has already acted in reliance on it.
7. The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is provided. An example given by the final rule of an expiration event or condition is upon the death of the patient. The form may not use “until revoked” by the signer as the expiration.
8. The signature of the patient and, when required for a patient who is a minor, the signature of an individual authorized to give consent; or, when required for a patient who is incompetent or deceased, the signature of an individual authorized to sign. Electronic signatures are permitted to the extent that they are not prohibited by any applicable law.
9. The date on which the consent is signed.

While these nine elements are required, the program may add additional elements to the consent form which are not contradictory to these required elements.

Final Rule changes

- *§2.31 Consent requirements. When using a general designation in the “To Whom” section, the patient has a right to request and obtain a list of disclosures by entity. This section now also permits electronic signatures on the consent form, if allowed by state law. In the final rule, table 1 is a list of individuals and entities. This table provides information regarding designating individuals and organizations in the “To Whom” section.*
- *Old §2.31(a)(5) Amount and Kind, is updated by §2.31(a)(3) by explicitly describing the substance use disorder-related information to be disclosed.*

Slide 4.4 Disclosures

The program may disclose patient information based on the consent form. Further, a program may make disclosures under two other circumstances: to prevent multiple enrollments and to elements of the criminal justice system which have referred patients. Click the buildings icon or the judge icon for specifics of these circumstances.

Multiple Enrollments

Disclosure may be made by the program to a central registry or any withdrawal management or maintenance treatment program not more than 200 miles away. The purpose of this is to prevent patients from enrolling in multiple programs. The consent form must list the central registry and each known withdrawal management or maintenance treatment programs to which the information will be disclosed. There is an option to word the consent to authorize "disclosure to any withdrawal management or maintenance treatment program established within 200 miles of the program," rather than individually listing all the programs.

The disclosure may be made when the patient is accepted for treatment, the type or dosage or the drug is changed, or treatment is interrupted, resumed, or terminated. The only information which may be disclosed is patient identifying information, the type and dosage of drug, and the relevant dates.

The central registry may disclose the name, address, and phone number of the member program in which the patient is enrolled. The member programs may then communicate to as many programs as necessary to verify the patient identification to prevent multiple enrollments.

Elements of the Criminal Justice System

If a patient is required by the criminal justice system to participate in a part 2 program as a condition of the disposition of criminal proceedings, the patient's information may be disclosed to individuals who need the information to monitor the patient's progress. For example, this individual may be a prosecuting attorney, a court, or a probation or parole officer. The expiration of consent to disclosure to the criminal justice system must be on the patient consent form. The expiration of this consent considers the anticipated length of treatment, the type of criminal proceeding involved and when final disposition will occur, and to whom disclosure will be made.

The individual in the criminal justice system who receives this information may only redisclose this information to the extent it is necessary to perform their official duties.

Final Rule changes

- *§2.34 Disclosures to prevent multiple enrollments. Updated terminology and moved definitions to §2.11.*
- *§2.35 No changes were made to this section.*

Slide 4.5 Disclosures without Patient Consent

There are three circumstances under which disclosure may be made without patient consent: in medical emergencies, for research, and for audit and evaluation. Each of these circumstances has specific requirements. Click each picture for the details.

Medical Emergencies

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.

In the comments on the final rule, SAMHSA gives no definition or guidance on what constitutes a "bona fide medical emergency." SAMHSA may provide subregulatory guidance at a later date. The phrase "informed consent cannot be obtained" does not mean the patient is able but will not give consent. "[C]annot be obtained" means the patient is incapable of giving consent.

Immediately following the disclosure, the part 2 program must document in the patient's records in writing the name of the medical personnel to whom the disclosure was made; the personnel's relationship to the facility if any; the name of the person making the disclosure; the date and time of the emergency; and the nature of the emergency.

A special rule permits disclosure to medical personnel of the Food and Drug Administration (FDA) if there is a belief the health of the individual may be threatened by a product regulated by the FDA. Such information may only be used by the FDA and must be documented as any other medical emergency.

Research

Under some conditions a part 2 program may release patient identifying information for the purpose of conducting scientific research. This is covered in section 2.52 of the regulations. A number of requirements must be met prior to releasing the information. If research data is sought, the program director should become familiar with the requirements.

Audit and Evaluation

During an audit or evaluation, patient records may not be downloaded, copied or removed from the part 2 program premises. Additional requirements for audit and evaluation are found in section 2.53 of the regulations.

Final Rule changes

- *§2.51 Medical emergencies. Revised to give providers more discretion to determine when a "bona fide medical emergency" exists.*
- *§2.52 Research. Revises exception to permit data protected by 42 CFR part 2 to be disclosed to qualified personnel for the purpose of conducting research by a part 2 program or any other individual or entity that is in lawful possession of part 2 data, if the researcher submits documentation meeting certain requirements related to other existing programs for human research. Also addresses data linkages to enable researchers holding part 2 data to obtain linkages to other datasets, provided the appropriate safeguards are in place.*
- *§2.53 Audits and evaluations. Modernizes requirements including paper and electronic records. Also permits audit or evaluation necessary to meet requirements of Centers for Medicare & Medicaid Services (CMS)-regulated accountable care organizations (ACOs) or similar CMS-regulated organizations (including a CMS-regulated Qualified Entity (QE)), under certain conditions.*

Slide 4.6 Court Orders Authorizing Disclosure and Use

An order by a court of competent jurisdiction must limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order, limit disclosure to persons with a need to know, and include measures to limit disclosure for the protection of the patient, the physician-patient relationship, and the treatment services. The program is not compelled to disclose the information unless a subpoena is also received.

Court orders may not authorize information to be disclosed by persons who have received the information for research purposes if the purpose of the order is to conduct a criminal investigation or prosecution of a patient. The information may be released if it is to investigate the qualified personnel holding the research records.

Final Rule changes

- *Subpart E – Court Orders Authorizing Disclosure and Use. No changes were made to this subpart.*

Slide 4.7 Court Orders – Confidential Communications

Confidential communications by patients in the course of diagnosis, treatment, or referral may be made if the disclosure is:

1. Necessary to protect against an existing threat to life or serious bodily injury, including suspected child abuse and neglect and verbal threats against third parties.
2. Necessary in investigation or prosecution of an extremely serious crime allegedly committed by the patient, for example homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse or neglect.
3. In connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the confidential communications.

In the event of orders authorizing disclosures for noncriminal purposes, the patient and person from whom the records are sought must have adequate notice and an opportunity to file a written response to the order. Any review of evidence must be held in a manner that ensures patient identifying information is not disclosed to anyone other than a party to the proceedings. Further, there must be no other way of obtaining the information, and public interest must outweigh the potential injury to the patient.

Slide 4.8 Court Orders – Investigation of Part 2 Programs

Court orders may authorize investigation of a part 2 program for either civil or criminal activities. Further, court orders may authorize placement of an undercover agent or informant if employees or agents of a part 2 program are believed to be engaged in criminal misconduct. Additional limitations exist and are found in sections 2.66 and 2.67 of the regulations.

Slide 4.9 Activity

On the patient consent form, wording may reflect that limited patient identifying information may be disclosed to prevent multiple enrollments. The consent form indicating who the information will be disclosed to:

May use phrasing indicating all withdrawal management programs within 200 miles

Must state information will only be released to a central registry

Must list the names and addresses of all other withdrawal management programs

Slide 4.10 Activities

42 CFR part 2 allows disclosure of patient information if a bona fide medical emergency exists and the patient cannot give consent. A bona fide medical emergency is defined by the final rule as:

A circumstance where brain damage may occur

A life or death situation

A life or death situation and a circumstance where brain damage may occur

The final rule does not define a bona fide medical emergency

Slide 4.11 Activity

Confidential communications by patients in the course of diagnosis, treatment, or referral may be made if the disclosure is:

Necessary to protect against an existing threat to life or serious bodily injury, including suspected child abuse and neglect and verbal threats against third parties

Necessary in investigation or prosecution of an extremely serious crime allegedly committed by the patient

In connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the confidential communications

Slide 4.12 Activity

The consent form must include a specific date when the consent expires.

True

False

Slide 5.1 Conclusion

Conclusion

Slide 5.2 Summary

All patients have a right to nondisclosure of their patient information unless consent to disclose information has been given under HIPAA rules. In an effort to encourage persons with a substance use disorder to participate in treatment, 42 CFR Part 2 goes further in restricting information which may be disclosed about patients.

If you work in a part 2 program or are authorized to receive patient information from a part 2 program, make sure you understand exactly who you may disclose information to and how much information may be disclosed. If you have questions, ask you supervisor, program administrator, or compliance officer to clarify the regulations for you.

Slide 5.3 Objective Review

You should now be able to:

- Name the primary acts which protect patient confidentiality
- Describe specific protections for persons seeking treatment for substance use disorder
- List the disclosures permissible with and without patient consent

This course will exit to your assessment upon completion of the timeline.

