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# Proposed Rule Updating the Substance Abuse Confidentiality Regulations (42 CFR Part 2)

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# Overview of Presentation



- Background on 42 CFR Part 2
- Why Revise the Current Regulations?
- SAMHSA Efforts Prior to the Proposed Rule
- Notice of Proposed Rulemaking (NPRM) Publication and Summary of Major Provisions

# Background on 42 CFR Part 2

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- Confidentiality of Alcohol and Drug Abuse Patient Records regulations (42 CFR Part 2)
    - Implements federal drug and alcohol confidentiality law (42 U.S.C. §290dd-2).
    - Protects confidentiality of the identity, diagnosis, prognosis, or treatment of any patient records maintained in connection with the performance of any federally assisted program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation or research.

# Background on 42 CFR Part 2



- The law and regulations were written during a time of great concern about the potential use of substance use disorder information against an individual.
- The purpose of 42 CFR Part 2 is to ensure that a patient receiving treatment for a substance use disorder in a Part 2 program is not made more vulnerable than an individual with a substance use disorder who does not seek treatment.

# Background on 42 CFR Part 2



- Applies to federally assisted “alcohol and drug abuse” programs.
- Patient consent must be obtained before sharing information from a program that is subject to 42 CFR Part 2.
- Once this information has been disclosed, no re-disclosure is permitted without the patient’s express consent to re-disclose or unless otherwise permitted under Part 2.

# Background on 42 CFR Part 2

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- Limited exceptions for disclosure without consent:
- Medical emergencies
  - Scientific research
  - Audits and evaluations
  - Child abuse reporting
  - Crimes on program premises or against program personnel
  - Court order
  - Communications with a qualified service organization (QSO) of information needed by the organization to provide services to the program

# Why Revise the Current Regulations?

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- Regulations first promulgated in 1975 and last substantively updated in 1987.
  - Significant changes have impacted health care delivery since then.
    - New models of integrated care that rely on information sharing to support coordination of patient care
    - Electronic infrastructure for information exchange
    - New focus on performance measurement
  - Concerns expressed about barriers to research.

# Why Revise the Current Regulations?

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- Breach of privacy of information protected by Part 2 can still lead to civil and criminal consequences for patients.
    - Loss of employment, housing, child custody
    - Discrimination by medical professionals and insurers
    - Arrest, prosecution and incarceration
  - Modernize the regulations and make them more understandable and less burdensome.

# SAMHSA Efforts Prior to Proposed Rule



- Funded one-year pilot project with five states to support exchange of health information among behavioral health and physical health providers.
- Developed (in conjunction with the Office of the National Coordinator for Health Information Technology) two sets of FAQs on the application of Part 2 within health information exchanges.
- Worked with ONC and other federal agencies on several projects to support behavioral health and health information exchange.

# SAMHSA Efforts Prior to Proposed Rule



- ➔ Held a Public Listening Session on June 11, 2014, to solicit feedback on the current Part 2 rules.
  - Announced in the Federal Register May 12, 2014 (79 FR 26929).
  - Comments were accepted until June 25, 2014.
  - Approximately 1,800 individuals participated in the session (in person or by phone).
  - SAMHSA received 112 oral comments and 635 written comments.

# NPRM Publication



- In addition to considering the wealth of public input received from the Listening Session, SAMHSA collaborated with its federal partner experts in developing the NPRM.
- NPRM published in the Federal Register on February 9, 2016 (81 FR 6988).

# NPRM Publication



→ HHS welcomes public comments.

- 60-day comment period
- Submit comments electronically via Federal eRulemaking Portal:  
(<http://www.regulations.gov>) or via one of the other methods outlined in the NPRM.
- Comments must be received no later than 5 p.m. on April 11, 2016.

# NPRM Major Provisions: General

- Proposed rule is intended to modernize the Part 2 rules by facilitating the electronic exchange of substance use disorder information for treatment and other legitimate health care purposes while ensuring appropriate confidentiality protections for records that might identify an individual, directly or indirectly, as having a substance use disorder.

# NPRM Major Provisions: General

- SAMHSA is proposing terminology changes throughout for clarity, consistency, and to modernize the regulations (e.g., from “alcohol and drug abuse” to “substance use disorder”).
  - SAMHSA proposes to change the name of the regulations to: **Confidentiality of Substance Use Disorder Patient Records.**

# NPRM Major Provisions: Applicability

- Applicability (§2.12) – SAMHSA proposes to:
- Revise the definition of “program” so that it does not apply to either general medical facilities or general medical practices in certain circumstances.
    - Currently, in those circumstances, the definition does not apply to general medical facilities, but does apply to general medical practices.
  - Apply restrictions on disclosures to individuals and entities receiving patient records from other lawful holders of patient identifying information (in addition to Part 2 programs).

# NPRM Major Provisions: Consent Requirements

- Consent Requirements (§2.31) – SAMHSA proposes to:
- Allow, in certain circumstances, a patient to include a *general designation* in the “To Whom” section of the consent form.
    - Distinction between those with and without a treating provider relationship with the patient.
  - Seek comments on an alternative approach to the proposed required elements for the “To Whom” section of the consent form.

# NPRM Major Provisions: Consent Requirements

- Consent Requirements (§2.31) – SAMHSA proposes to:
- Require an explicit description of the amount and kind of substance use disorder treatment information.
  - Require the “From Whom” section to specifically name the Part 2 program or other lawful holder of patient identifying information making the disclosure.

# NPRM Major Provisions: Consent Requirements

- Consent Requirements (§2.31) – SAMHSA proposes to:
- Require the consent form to include two new statements that the patient understands:
    - the terms of their consent.
    - when using a general designation in the “To Whom” section, their right to obtain, upon request, a list of entities to whom their information has been disclosed, pursuant to the general designation (see §2.13).
  - Permit electronic signatures (to the extent that they are not prohibited by any applicable law).

# NPRM Major Provisions: Confidentiality Restrictions and Safeguards

- Confidentiality Restrictions and Safeguards (§2.13) – SAMHSA proposes to:
- Add a requirement that, upon request, patients who have included a general designation on their consent form must be provided a list of entities to whom their information has been disclosed pursuant to a general designation (List of Disclosures).
    - Applies to disclosures made in previous two years.
    - Effective two years after effective date of final rule.

# NPRM Major Provisions: Research

## → Research (§2.52) – SAMHSA proposes to:

- Permit Part 2 data to be disclosed to qualified personnel for the purpose of conducting scientific research by a Part 2 program or other lawful holder of Part 2 data if the researcher provides documentation of meeting certain requirements for existing protections for human subjects research (HIPAA and/or HHS Common Rule).
  - Currently, only program directors may authorize disclosure of Part 2 data for research purposes.

# NPRM Major Provisions: Research

## → Research (§2.52) – SAMHSA proposes to:

- Address data linkages to enable researchers holding Part 2 data to link to data sets from federal data repositories.
  - Supports more advanced research, including studies of longitudinal effects of patient treatments.
  - SAMHSA is seeking comments on expanding the data linkages provision to data sets from non-federal data repositories.
- Address the retention and disposal of Part 2 data used in research by referencing expanded §2.16, Security for Records.

# NPRM Major Provisions: Audit and Evaluation

- Audit and Evaluation (§2.53) – SAMHSA proposes to:
- Update Medicare and Medicaid audit or evaluation section to include Children’s Health Insurance Program (CHIP).
  - Permit the Part 2 program, not just the Part 2 program director, to determine who is qualified to conduct an audit or evaluation.
  - Include provisions for both paper and electronic patient records.

# NPRM Major Provisions: Audit and Evaluation

- Audit and Evaluation (§2.53) – SAMHSA proposes to:
- Permit an audit or evaluation necessary to meet the requirements (under certain conditions) of Centers for Medicare & Medicaid (CMS)-regulated accountable care organizations or similar CMS-regulated organizations (including CMS-regulated Qualified Entities).
  - Revise requirements for destroying records by referencing expanded §2.16, Security for Records.

# NPRM Major Provisions: Security for Records

- Security for Records (§2.16) – SAMHSA proposes to:
- Clarify that this section requires both Part 2 programs and other lawful holders of patient identifying information to have in place formal policies and procedures addressing security, including sanitizing associated media.
  - Address both paper and electronic records.
  - Replace relevant language in other sections with reference to the policies and procedures requirement in §2.16.

# NPRM Major Provisions: Disposition of Records by Discontinued Programs



- Disposition of Records by Discontinued Programs (§2.19) – SAMHSA proposes to:
- Address both paper and electronic records.
  - Add requirements for sanitizing associated media.

# NPRM Major Provisions: Medical Emergencies

- Medical Emergencies (§2.51) – SAMHSA proposes to:
- Revise the medical emergency exception to make it consistent with the statutory language and to give providers more discretion to determine when a “bona fide medical emergency” exists.
    - Currently, information may be disclosed without consent “for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.”

# NPRM Major Provisions: Notice to Patients of Federal Confidentiality Requirements

- Notice to Patients of Federal Confidentiality Requirements (§2.22) – SAMHSA proposes to:
- Clarify that the written summary of federal law and regulations may be provided to patients in either paper or electronic format.
  - Require the statement regarding the reporting of violations to include contact information for the appropriate authorities.

# NPRM Major Provisions: Reports of Violations



- Reports of Violations (§2.4) – SAMHSA proposes to:
  - Revise the requirement for reporting violations of Part 2 by methadone programs (now referred to as opioid treatment programs) to the Food and Drug Administration (FDA) because authority over these programs was transferred from the FDA to SAMHSA in 2001.

# NPRM Major Provisions: Prohibition on Re-disclosure

→ Prohibition on Re-disclosure (§2.32) – SAMHSA proposes to:

- Clarify that the prohibition on re-disclosure only applies to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder, and allows other health-related information shared by the Part 2 program to be re-disclosed, if permissible under other applicable laws.

# NPRM Major Provisions: Definitions

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- Definitions (§2.11) – SAMHSA proposes to:
    - Revise/clarify several current definitions. For example, the QSO definition was revised to:
      - Add “population health management” to the examples of services that a QSO may provide.
      - Change “medical services” to “medical staffing services.”

# NPRM Major Provisions: Definitions

- ➔ Definitions (§2.11) – SAMHSA proposes to:
  - Add five new definitions. For example:
    - “Treating provider relationship means that, regardless of whether there has been an actual in-person encounter, (a) a patient agrees to be diagnosed, evaluated and/or treated for any condition by an individual or entity and (b) the individual or entity agrees to undertake diagnosis, evaluation and/or treatment of the patient, or consultation with the patient, for any condition.”

# NPRM Major Provisions: Definitions

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- Definitions (§2.11) – SAMHSA proposes to:
    - Consolidate all but one definition in a single section (§2.11).
      - “Federally assisted” remains in the Applicability provision at §2.12 for the purpose of clarity.
    - Modernize terminology and ensure consistency of use across regulations.

# NPRM Publication

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- Comments must be received no later than 5 p.m. on April 11, 2016.