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

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Background on 42 CFR Part 2



- 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?



- 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.

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: Applicability

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- 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.

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: Confidentiality Restrictions and Safeguards

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- 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).

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.

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).

NPRM Publication



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