How to Navigate Proposed Changes on Substance Abuse Records

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42 CFR Part 2 Proposed Rules

- **Confidentiality of Substance Abuse Disorder Patient Records: Proposed Rule**
  - First proposed revision in nearly 30 years.
  - Published in Federal Register February 9, 2016.
  - Comments due April 11, 2016.

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42 CFR Part 2 Proposed Rules

- **Purpose of Proposed Revisions**
  - To facilitate the electronic exchange of substance use disorder information for treatment/health care.
  - Allow patients with substance abuse disorders to participate in alternative payment models and integrated health care models like accountable care organizations (ACO) and health homes.

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Objectives

- Provide overview of the revised regulations and where the biggest obstacles lie
  - » Changes to consent requirements.
  - » Definition of a Part 2 Program.
  - » Issues related to downstream subcontractors.
- Discuss
  - » Unresolved issues and potential impediments.
  - » Where HIPAA and the Part 2 Rule intersect and where they continue to require separate attention.
  - » Operational adjustments needed to prepare for changes.

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Proposed Revisions to Part 2 Rules

- Changes to Consent Form
  - » Currently, consent form must include name of individual or organization to whom disclosure is to be made.
  - » Under Proposed Rule, consent form would identify either:
    - Name of individuals.
    - Name of the entity for treating providers.
    - Name of the entity for third-party payers that require patient-identifying information for reimbursement.

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Proposed Revisions to Part 2 Rules

- **Changes to Consent Form For Intermediaries**
  - If entity does not have treating relationship, such as an Health Information Exchange (HIE), Accountable Care Organization (ACO), Coordinated Care Organization (CCO), or a research institution, the name of the entity, and
    - The name of an individual participant,
    - The name of an entity participant that has a treating provider relationship with the patient, or
    - A general designation of an individual or entity participant or class of participants with treating provider relationship.

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Proposed Revisions to Part 2 Rules

- **Conditions for General Designation**
  - » Form must include an explicit description of the amount and kind of substance use disorder treatment information that may be disclosed.
  - » The consent form must include statements that patient may receive an accounting of disclosures, and that patient understands terms of consent form.
  - » The name of the Part 2 program or other lawful holder of the patient identifying information must be specifically named.

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Proposed Revisions to Part 2 Rules

- Operational Requirements for Consent
  - » HIE, ACO or other non-treating entity intermediary must have mechanisms to determine whether providers are treating providers, such as
    - Provider attestation.
    - Patient Portal.
  - » Electronic signatures to be permitted.

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Proposed Revisions to Part 2 Rules

- Application to General Medical Practices
  - » Clarify that the definition of "Program" would *not* apply to "general medical facilities" and "general medical practices,"
    - Unless an *identified unit* within a general medical facility or general medical practice *holds itself out as providing, and provides*, substance use disorder diagnosis, treatment, or referral for treatment, or
    - If the *primary function of medical personnel or other staff* in the general medical facility or general medical practice is the provision of such services and they are *identified as providing such services*.

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Proposed Revisions to Part 2 Rules

- "Holds itself out" means
  - Any activity that would lead one to reasonably conclude that the individual or entity provides substance use disorder diagnosis, treatment, or referral for treatment:
    - 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.

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Proposed Revisions to Part 2 Rules

- Qualified Service Organizations (QSO)
  - Clarify that population health management is a service that may be offered by a QSO.
    - Care coordination is not a QSO service.
  - Patient records could be disclosed under a QSO agreement (QSOA) to the office/unit responsible for population health management in an organization like an ACO, health home, or managed care organization.
  - QSO cannot disclose Part 2 Program data to other participants.

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Proposed Revisions to Part 2 Rules

- Guidance states that QSO may disclose to contract agent as necessary to provide the services described in the QSOA.
  - » As long as the agent only discloses the information back to the QSO or the Part 2 Program from which the information originated,
  - » Agrees to be bound by Part 2 requirements.

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Proposed Revisions to Part 2 Rules

- Medical Emergency
  - » Aligns the definition of "medical emergency" with the statutory definition of a "bona fide" medical emergency.
    - Would permit patient identifying information to 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.

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Proposed Revisions to Part 2 Rules

- Prohibitions on Re-disclosure
  - » Clarifies that restriction 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.
    - Would allow re-disclosure of other health-related information disclosed by a Part 2 program.

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Proposed Revisions to Part 2 Rules

- Research Disclosures
  - » Currently, only Part 2 Program Director may disclose patient identifying information for research.
  - » Proposed Rule would allow any individual in lawful possession of data to disclose patient identifying information to qualified research personnel for the purpose of conducting scientific research, provided . . .

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Proposed Revisions to Part 2 Rules

- Conditions
  - » Satisfaction of Privacy regulations under HIPAA, and
  - » Regulations for the protection of human subjects under the Common Rule.
- Would also enable researchers holding Part 2 data to link to data sets from federal data repositories.

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Proposed Revisions to Part 2 Rules

- Notice
  - » Requirement to provide patients with a written notice of Part 2 requirements continues.
  - » Under Proposed Rule, must be in paper or electronic format.
    - Information regarding contact information to report violations.
    - Encourage Part 2 Programs to consider providing notice in languages other than English.

Conclusion

- If we were unable to answer your question, we will respond via email
- Please feel free to contact today's presenters with additional questions
- Thank you for your participation in today's webinar