42 C.F.R. Part 2 - Notice of Proposed Rulemaking

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42 C.F.R. Part 2 Overview

- Applies to federally assisted "alcohol and drug abuse" programs
- The goal of 42 C.F.R. Part 2 – took effect in 1975 and was last substantively updated in 1987 – is to ensure that patients receiving substance use disorder treatment in a Part 2 program are not made more vulnerable than an individual with a substance use disorder who does not seek treatment
- Patient consent must be obtained before sharing information from a Part 2 program, and re-disclosure also requires express consent

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Process

- Listening Session was held on June 11, 2014
  - Approximately 1,800 individuals participated
  - SAMHSA received 112 oral comments and 635 written comments
- NPRM published on February 9, 2016
  - 60-day comment period
  - Comments must be received no later than 5:00 p.m. on April 11, 2016
  - eRulemaking Portal: http://www.regulations.gov

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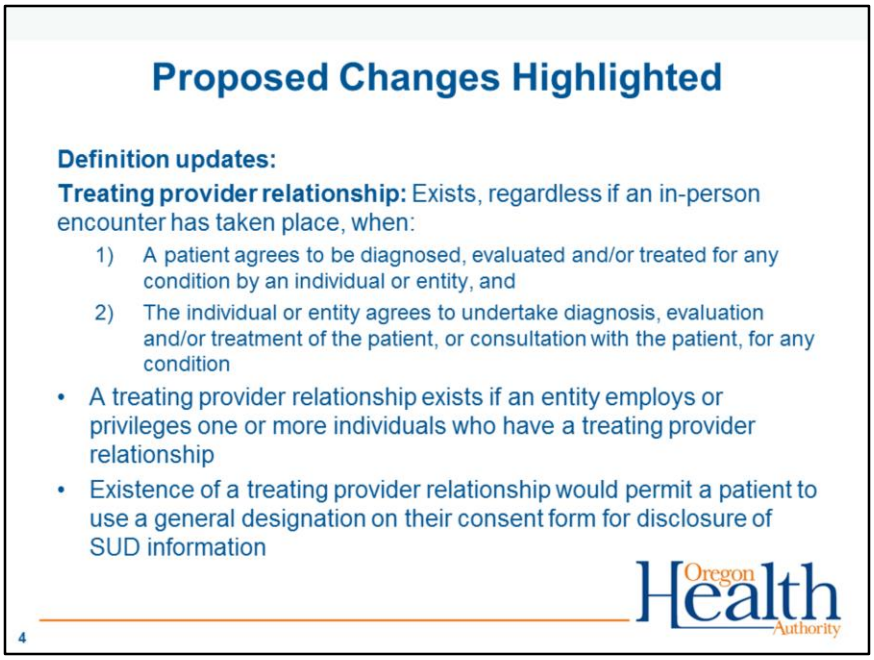
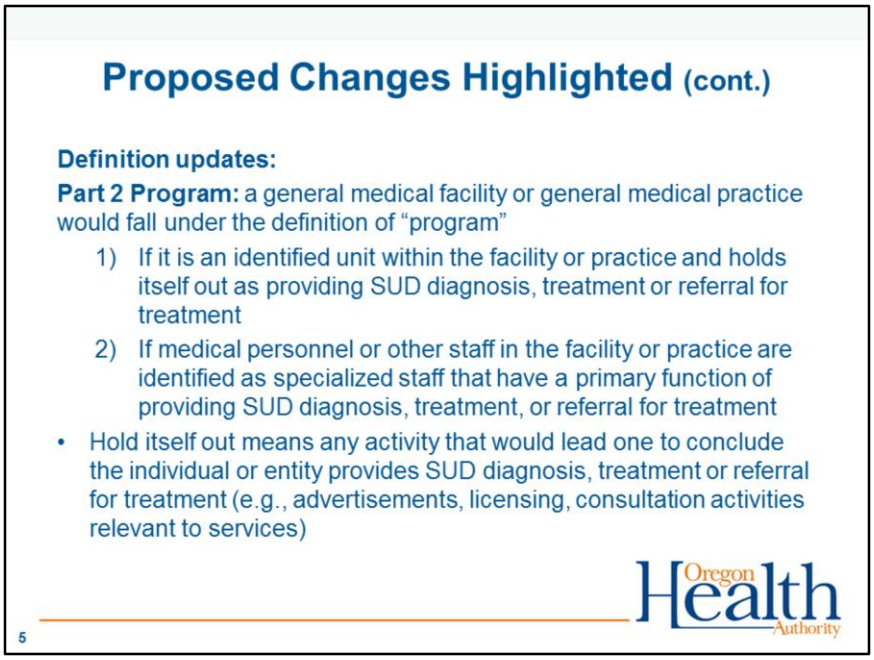


Other points: Patients may further designate their treating providers as “past,” “current,” and/or “future” treating providers. In addition, a patient may designate, by name, one or more individuals on their health care team with whom they do not have a treating provider relationship.



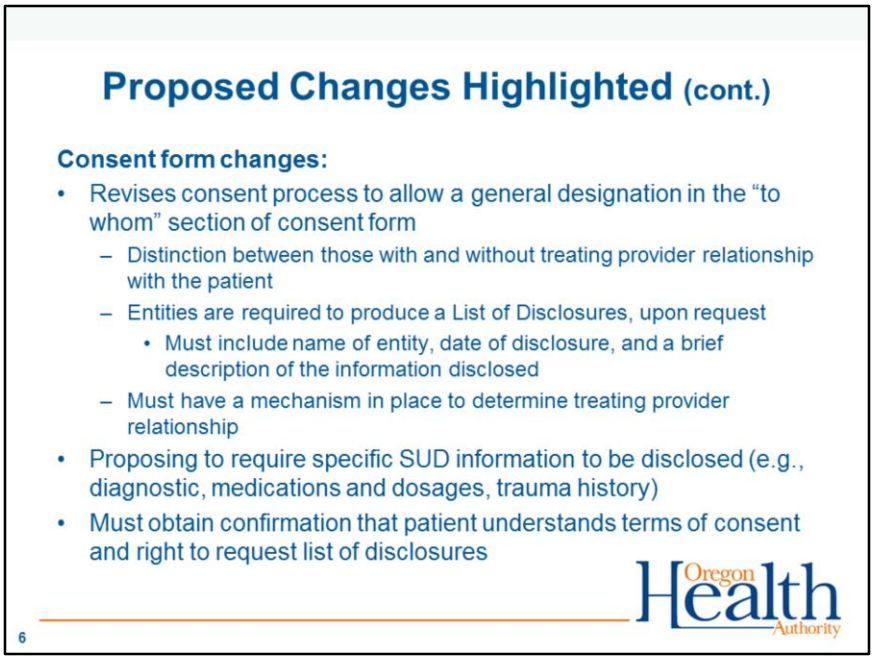
Currently the program definition does not apply to general medical facilities but does apply to general medical practices

If a provider is not a general medical facility or general medical practice, then the provider meets the Part 2 definition of a "program" if it is an individual or entity who holds itself out as providing, and provides substance use disorder diagnosis, treatment, or referral for treatment.

If the provider is an identified unit within a general medical facility or general medical practice, it is a "program" if it holds itself out as providing, and provides, substance use disorder diagnosis, treatment or referral for treatment.

If the provider consists of medical personnel or other staff in a general medical facility or general medical practice, it is a "program" if its primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and is identified as such specialized medical personnel or other staff by the general medical facility or general medical practice.

SAMHSA states that hospitals, trauma centers, or federally qualified health centers would all be considered "general medical facilities." Primary care providers who work in such facilities would be covered if: (1) they work in an identified unit within such general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment or referral for treatment, or (2) the primary function of the providers is substance use disorder diagnosis, treatment or referral for treatment and they are identified as providers of such services by the general medical facility.



SAMHSA is proposing to require the consent form to explicitly describe the substance use disorder-related information to be disclosed. The types of information that might be requested include diagnostic information, medications and dosages, lab tests, allergies, substance use history summaries, trauma history summary, employment information, living situation and social supports, and claims/encounter data. The designation of the "Amount and Kind" of information to be disclosed must have sufficient specificity to allow the disclosing program or other entity to comply with the request. For example, the description may include: "medications and dosages, including substance use disorder-related medications," or "all of my substance use disorder-related claims/encounter data." An example of an unacceptable description would be "all of my records."

Proposed Changes Highlighted (cont.)

Consent Form Designation in the To Whom Section		
Treating provider relationship?	Primary designation	Additional designation
Y	Name of individual(s) (e.g., Jane Doe)	None
N	Name of individual(s)	None
Y	Name of entity (e.g., Lakeview County Hospital)	None
N	Name of entity that is a third party payer (e.g., Medicare)	None
N	Name of entity without treating provider relationship and not a payer (e.g., HIE or research institution)	1) Name(s) of an individual participant(s) 2) Name(s) of an entity participant with treating provider relationship 3) A general designation of an individual or entity participant(s) with treating provider relationship (e.g., my current and future providers)

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Under the last proposal, the consent form could not include the general function "HIE" without specifying the name of the HIE entity used by the treating provider.

Proposed Changes Highlighted (cont.)

- Revises definition of Qualified Service Organization (QSO) to include population health management as an qualified service
  - Population health management is defined as "increasing desired health outcomes and conditions through monitoring and identifying individual patients within a group"
  - Under a QSOA, a Part 2 program can share information with the unit/office carrying out the population health management service but consent is needed to share with other organization participants (e.g. network providers)
  - SAMHSA expressly excluded care coordination from the list of qualified services as it has a "patient treatment component"

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Proposed Changes Highlighted (cont.)

- Clarifies that prohibition on re-disclosure only applies to information that would identify an individual as having received SUD treatment
  - May redisclose other health-related information
- Revises medical emergency exception to give providers more discretion to determine when a bona fide emergency exists
  - Must continue to require documentation when records are accessed
  - Part 2 program must consider if the HIE has technology, rules and procedures to protect PHI

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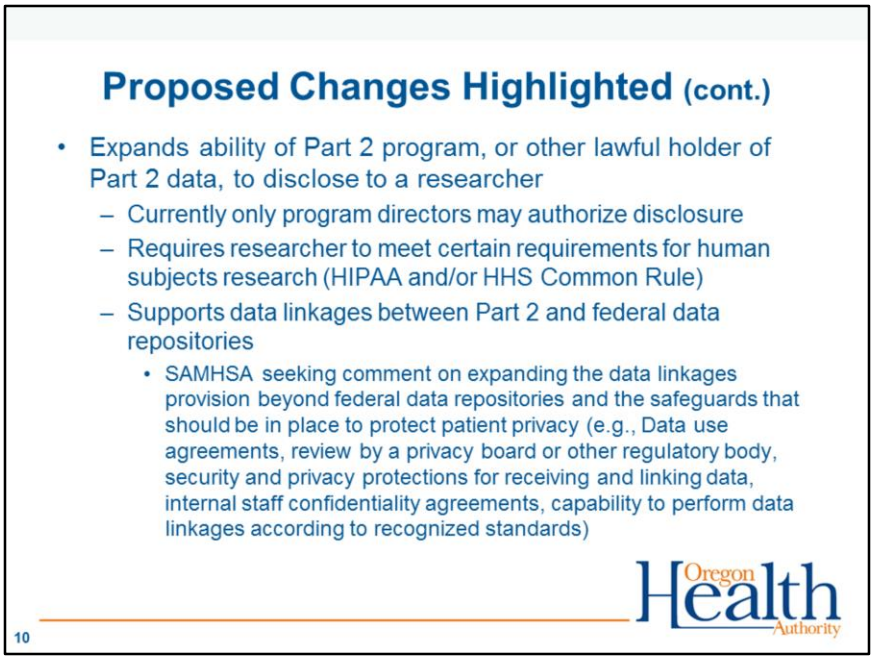

Researchers will need to be a HIPAA covered entity or business associate or subject to the HHS Common Rule