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

Veronica Guerra, Policy Analyst



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

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>

Proposed Changes Highlighted

Definition updates:

Treating provider relationship: Exists, regardless if an in-person encounter has taken place, when:

- 1) A patient agrees to be diagnosed, evaluated and/or treated for any condition by an individual or entity, and
 - 2) The individual or entity agrees to undertake diagnosis, evaluation and/or treatment of the patient, or consultation with the patient, for any condition
- A treating provider relationship exists if an entity employs or privileges one or more individuals who have a treating provider relationship
 - Existence of a treating provider relationship would permit a patient to use a general designation on their consent form for disclosure of SUD information



4

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.

Proposed Changes Highlighted (cont.)

Definition updates:

Part 2 Program: a general medical facility or general medical practice would fall under the definition of “program”

- 1) If it is an identified unit within the facility or practice and holds itself out as providing SUD diagnosis, treatment or referral for treatment
 - 2) If medical personnel or other staff in the facility or practice are identified as specialized staff that have a primary function of providing SUD diagnosis, treatment, or referral for treatment
- Hold itself out means any activity that would lead one to conclude the individual or entity provides SUD diagnosis, treatment or referral for treatment (e.g., advertisements, licensing, consultation activities relevant to services)



5

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.

Proposed Changes Highlighted (cont.)

Consent form changes:

- Revises consent process to allow a general designation in the “to whom” section of consent form
 - Distinction between those with and without treating provider relationship with the patient
 - Entities are required to produce a List of Disclosures, upon request
 - Must include name of entity, date of disclosure, and a brief description of the information disclosed
 - Must have a mechanism in place to determine treating provider relationship
- Proposing to require specific SUD information to be disclosed (e.g., diagnostic, medications and dosages, trauma history)
- Must obtain confirmation that patient understands terms of consent and right to request list of disclosures



6

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)	<ol style="list-style-type: none"> 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)

7

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”

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

Proposed Changes Highlighted (cont.)

- Expands ability of Part 2 program, or other lawful holder of Part 2 data, to disclose to a researcher
 - Currently only program directors may authorize disclosure
 - Requires researcher to meet certain requirements for human subjects research (HIPAA and/or HHS Common Rule)
 - Supports data linkages between Part 2 and federal data repositories
 - SAMHSA seeking comment on expanding the data linkages provision beyond federal data repositories and the safeguards that should be in place to protect patient privacy (e.g., Data use agreements, review by a privacy board or other regulatory body, security and privacy protections for receiving and linking data, internal staff confidentiality agreements, capability to perform data linkages according to recognized standards)

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