



What Substance Use Treatment Providers Should Know About Changes to Confidentiality Regulations (42 CFR Part 2) – Final Rule¹

February 15, 2017

On January 18, 2017, the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (“SAMHSA”) issued a [Final Rule](#) amending 42 CFR Part 2 (“Part 2”), the federal substance use disorder confidentiality regulations.² The Final Rule was scheduled to take effect on February 17, 2017, but the Trump administration put all new and pending regulations -- including this Final Rule -- on hold until at least March 20, 2017.³

This fact sheet describes the changes made by the Final Rule which substance use treatment providers should be prepared to address by March 20th, which is when changes will go into effect if there is no further action by the Trump administration. The primary objective of this fact sheet is to inform substance use treatment providers of those changes in the Final Rule that are most likely to impact them, so that they will be able to comply with updated confidentiality requirements as soon as the changes become effective. This fact sheet is not a complete review of the changes made by the Final Rule, so stakeholders should review the new regulations in their entirety and consult the Legal Action Center (“LAC”)’s future updates, sample forms, and publications at this [link](#).

WHAT THINGS HAVE NOT CHANGED?

1. Who must follow Part 2:

- Part 2 still applies only to federally-assisted “programs,” as defined in 42 CFR §§ 2.11 and 2.12.

2. What information is protected by Part 2:

- Part 2 still protects information that would identify a patient, either directly or indirectly, as having or having had a substance use disorder, or being or having been a patient in a federally-assisted “program.”

3. How information protected by Part 2 can be disclosed:

- Information protected by Part 2 still may not be disclosed without written patient consent or unless another exception applies (and there are no new exceptions).

4. The prohibition on re-disclosure:

- The prohibition on re-disclosure still applies to information protected by Part 2.

¹ 82 Fed. Reg. 6052 (Jan. 18, 2017). 42 CFR Part 2 is the regulation for the authorizing statute, 42 U.S.C. 290dd-2.

² 81 Fed. Reg. 6988 (Feb. 9, 2016).

³ Reince Priebus, White House Chief of Staff, Memorandum for the Heads of Executive Departments and Agencies, Jan. 20, 2017, available at <https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies>.

WHAT THINGS HAVE CHANGED?

1. Consent Options - § 2.31:

- While patient consent is still required to disclose Part 2-protected information (unless another exception applies), the form of that consent has changed under the Final Rule.
- To Whom: Previously, the “to whom” section of the consent form could list the name or the title of the individual or the name of the organization to which the disclosure was to be made. Under the Final Rule, there are more options for filling out the “to whom” section. A patient can now list any of the following in the “to whom” section:
 - the name of an individual;
 - the name of an entity which has a “treating provider relationship”⁴ with the patient;
 - the name of an entity with which the patient does not have a treating provider relationship and which is a third-party payer; and/or
 - the name of an entity with which the patient does not have a treating provider relationship and which is not a third-party payer (such as a health information exchange), plus either:
 - the name(s) of specific individual participant(s), or
 - the name(s) of an entity participant(s) with which the patient has a treating provider relationship, or
 - a general designation of participants with which the patient has a treating provider relationship (e.g., “all my treating providers”).
- Amount & Kind: SAMHSA revised the regulations to require the section of the consent form that lists the Amount and Kind of information to be disclosed to be more specific. The consent form must now explicitly describe the substance use disorder-related information to be disclosed, and with sufficient specificity to allow the disclosing program or other entity to comply with the request.
 - For example, it would be permissible to state, “all of my substance use disorder records” in the Amount and Kind section of the Part 2 consent form, as long as more granular options are also included. It would not be permissible to state “all of my records” in the Amount and Kind section.

2. Qualified Service Organization (“QSO”):

- SAMHSA has revised the definition of QSO to include population health management in the list of examples of services a QSO may provide.
- SAMHSA also clarified that QSO Agreements (“QSOAs”) may be used to provide “medical staffing services” -- for example, contracting with a provider of on-call coverage services—but a QSOA may not be used to provide general “medical services”—for example, treatment by a primary care doctor. SAMHSA made this revision to emphasize that QSOAs should not be used to avoid obtaining patient consent.

⁴ See definition of “treating provider relationship” in the Definitions section below.

- Care coordination was not added to the list of examples of permissible services offered by QSOs since care coordination has a patient treatment component.

3. Security for Records - § 2.16:

- The Final Rule creates more detailed requirements for protecting the security of records. Specifically, Part 2 now requires that both Part 2 programs and lawful holders have established formal policies and procedures for the security of both paper and electronic records. The new security requirements align more closely with those of the HIPAA Security Rule.

4. Revised and New Definitions - § 2.11:

The Final Rule revises and clarifies existing definitions and provides new definitions of important terms in the regulation. Some examples of this include:

A. Treating Provider Relationship

- A “treating provider relationship” means that, regardless of whether there has been an actual in-person encounter:
 - A patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treated, or agrees to accept consultation, for any condition by an individual, or entity, and;
 - The individual or entity undertakes or agrees to undertake diagnosis, evaluation, and/or treatment of the patient, or consultation with the patient, for any condition.⁵
- The revised consent options permit certain types of disclosures only when the recipient has a “treating provider relationship” with the patient.⁶

B. Lawful Holder

- A “lawful holder” of patient identifying Part 2 information is an individual or entity who has received such information as the result of a Part 2-compliant patient consent (with a prohibition on re-disclosure notice) or as a result of one of Part 2’s exceptions to the consent requirements.
 - The Final Rule requires lawful holders of patient identifying Part 2 information (e.g., patients’ treating providers, hospital emergency rooms, insurance companies, an individual or entity performing an audits or evaluations, and individuals or entities conducting scientific research) to be bound by the requirements of Part 2.

5. List of Disclosures Requirement - § 2.13(d):

- To balance the increased flexibility in Part 2’s consent provisions, the regulations now require that patients who have included a general designation in the “To Whom” section of their consent form be provided, upon request, a list of entities to which their information has been disclosed through pursuant to that general designation. This “List of Disclosures” must be provided by the

⁵ “Agrees” as used in the definition does not necessarily mean imply a formal written agreement. An agreement might be evidenced by making an appointment or by a telephone conversation.

⁶ See additional explanation in the Consent section of this publication.

entity that serves as an intermediary between the Part 2 program and the ultimate recipients, such as a Health Information Exchange.

- When a general designation is used in the “To Whom” section of the consent form, a statement must be included on the consent form that informs the patients that they have a right to receive a list of entities to which their patient-identifying Part 2 information has been disclosed pursuant to the general designation.
- The patient’s request for a list of disclosures must be in writing (either electronic or paper documentation).

6. Research - § 2.52:

- The Final Rule changes the process for disclosing Part 2-protected information to researchers, aligning Part 2’s research exception more closely with HIPAA’s.

7. Notice to Patients of Federal Confidentiality Requirements - Contact Information for Complaints of Violations - § 2.22(b)(2):

- The Final Rule adds a required element to the written notice of confidentiality rights, which Part 2 programs are required to provide to patients upon admission. The written notice must now include contact information for the authorities to whom patients can report violations of Part 2.

IMPORTANT ADDITIONAL INFORMATION:

A. On January 18, 2017, SAMHSA also issued a [Supplemental Notice of Proposed Rulemaking](#) (“SNPRM”) to seek comments on additional proposed changes to the Final Rule. Like the Final Rule, the SNPRM has also been put on hold by the Trump administration until at least Mar. 20, 2017. Although the SNPRM states that February 17th is the submission deadline for comments, it is unclear whether this deadline is also subject to the regulatory delay. Nevertheless, the Legal Action Center [submitted](#) comments on the proposed changes on February 13, 2017. We encourage all stakeholders to [submit comments](#) on the SNPRM before the stated February 17th deadline, and have provided a [template](#) that organizations and individuals can use to construct comments for submission. The SNPRM requests further comments on issues such as:

- payment and health care operations-related disclosures that can be made to contractors, subcontractors, and legal representatives by lawful holders under the Part 2 consent provisions;
- audit and evaluation-related disclosures that can be made to contractors, subcontractors, and legal representatives;
- the appropriate safeguards for lawful holders and their contractors, subcontractors, and legal representatives’ use and disclosure of patient-identifying Part 2 information; and

- the appropriateness of an abbreviated prohibition on re-disclosure notice for contractors, subcontractors, and legal representatives, and the circumstances (if any) this abbreviated notice can be used.
- B. LAC's detailed analysis of the Final Rule will not be released to stakeholders until more guidance is available from the Trump administration regarding when and how the Final Rule will take effect.
- C. Updates to LAC's 2012 Confidentiality Law Guide:
- Once the Final Rule becomes effective, LAC plans to incorporate the new regulations in our book, *Confidentiality and Communication: A Guide to the Federal Drug & Alcohol Confidentiality Law and HIPAA*.
 - Details on ordering the *Guide* can be found [here](#). To receive updates about the release of the *Guide* and other confidentiality resources and training by the Legal Action Center, sign up at <https://lac.org/subscribe/>.