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an interview with
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SAMHSA publishes final rule revising 42 CFR Part 2

- » The final rule is the first substantive revision to 42 CFR Part 2 (Confidentiality of substance use disorder patient records) since 1987.
- » The final rule is in part an effort to modernize Part 2 in light of significant technological and regulatory changes in the healthcare industry.
- » In the final rule, Substance Abuse and Mental Health Services Administration (SAMHSA) also announced that it was issuing a Supplemental Notice of Proposed Rulemaking (SNPRM).
- » Whether the final rule goes far enough to modernize Part 2 and address all stakeholder concerns remains to be seen.
- » Part 2 programs must review and revise Part 2 consent forms, consider revising their policies and procedures, and do further training based on the various changes coming from the final rule.

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When people think of patient privacy laws, they usually think of the privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Although HIPAA is ubiquitous in the healthcare industry, there is an equally important patient privacy law for providers who treat substance abuse disorders. The Confidentiality of Alcohol and Drug Abuse Patient Records regulations found at 42 CFR Part 2, colloquially known as Part 2 or the Part 2 regulations, protect the confidentiality of substance use disorder patient records for federally assisted substance use disorder programs.



Bossenbroek

On January 18, 2017, for the first time in almost 30 years, the Substance Abuse and Mental Health Services Administration (SAMHSA) issued its final rule attempting to

update and modernize Part 2.¹ The final rule took effect on March 21, 2017, and aside from technical, non-substantive, and nomenclature changes to Part 2, the rule finalized approximately a dozen amendments published in the proposed rule the year before. This article will discuss some of more significant amendments and how they may impact compliance for providers who are subject to Part 2.

Background of Part 2

Part 2 regulations originate from two federal statutes passed in the 1970s—the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 and the Drug Abuse Prevention, Treatment, and Rehabilitation Act of 1972. The purpose of Part 2 was to ensure that individuals who receive treatment for a substance use disorder in a Part 2 program were not made more vulnerable by reason of the availability of their records than individuals who do not seek treatment for a substance use disorder.

Underlying this purpose was the concern that the availability of information related to an individual's substance use disorder carries the risks of job loss, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution, and incarceration. By protecting the confidentiality of this information, Part 2 exists to encourage these individuals seek, rather than avoid, treatment.

Part 2 applies only to a federally-assisted program. Both "program" and "federally-assisted" are carefully defined terms in Part 2. Not all providers or entities that treat substance abuse disorders are subject to Part 2, because they may not meet either or both of these definitions. In contrast to the broader use and disclosure provisions of HIPAA, Part 2 strictly prohibits the disclosure of patient records unless the patient executes a written consent or the disclosure falls within one of the narrow circumstances where Part 2 permits a disclosure without patient consent. These narrow circumstances include disclosures made:

- ▶ to medical personnel in a medical emergency;
- ▶ to qualified personnel for research, audit, or program evaluation purposes; or
- ▶ pursuant to a Part 2-compliant court order.

Other recognized exceptions include communications:

- ▶ within the Part 2 program among personnel who need the information relating to the patient's diagnosis, treatment, or referral for treatment;
- ▶ between a program and a qualified service organization (QSO);
- ▶ to law enforcement regarding crimes on the care program's premises or against program personnel; and
- ▶ reporting suspected child abuse and neglect.

Part 2 has gone largely unchanged in the last 30 years, but the healthcare system and the world of healthcare information technology has not.² For example, new models of integrated care have emerged that rely on information sharing to facilitate the coordination of patient care, and this information is now in large part managed and exchanged electronically. As noted earlier, the privacy and security regulations enacted under HIPAA and the Health Information Technology for Economic and Clinical Health Act (HITECH Act) impose an additional layer of compliance requirements for Part 2 programs that are required to comply with both Part 2 and HIPAA/HITECH. In June 2004, SAMHSA published a white paper discussing the interplay and overlap of Part 2 and HIPAA's Privacy Rule.³

Summary of major changes

Responding to requests from stakeholders seeking the modernization of Part 2, SAMHSA published a Notice of Proposed Rulemaking on February 9, 2016 that preceded the final rule.⁴ Although space does not allow discussion of all the amendments and notable commentary in the final rule, what follows are some of the important changes for Part 2 programs that care providers must be aware of.

Consent

Perhaps the most significant change introduced by the final rule involved the Part 2 consent requirements. Part 2 consent requires, among several other things, the name or title of the individual or the name of the organization to which disclosure is to be made ("To Whom"), and how much and what kind of information is to be disclosed ("Amount and Kind").

The final rule substantially revised the "To Whom" requirements to allow, in theory, for a more general designation of the recipients.

SAMHSA introduced the phrase “treating provider relationship” that may exist between the patient and the recipient of the disclosure: To categorize the requirements for the “To Whom” section of the consent:

- ▶ If the disclosure is made to an individual, whether that individual has a treating provider relationship with the patient or not, only the individual’s name must be listed. No further designation is required.
- ▶ If the disclosure is made to an entity that has a treating provider relationship with the patient, then the consent form is required to list only the name of the entity.

If the disclosure is to an entity that does not have a treating provider relationship with the patient, the consent requirements are a bit more complex. If the entity is a third-party payer, then only the name of the payer needs to be listed.

If the disclosure is being made to an entity that does not have a treating relationship with the patient and is not a third-party payer, such as an entity that facilitates the exchange of health information (e.g., an HIE) or a research institution, then the consent must set forth the name of this entity and must designate an additional person or entity affiliated with this entity to whom the entity is authorized to disclose the patient information. The permitted designations are:

- ▶ the name of an individual or individuals participating in that entity (e.g., a physician who is affiliated with a research entity),
- ▶ the name of an entity participant that has a treating provider relationship with the patient (e.g. a hospital that participates in an HIE), or
- ▶ a general designation of an individual or entity or class of participants who have a treating relationship with the patient (e.g., “my current and future treating providers”).

Upon written request, patients who have consented to disclosure using a general designation in the “To Whom” section are entitled to a list of those disclosures that have occurred within the previous two years. The list of disclosures must include the date of the disclosure and a brief description of the patient-identifying information disclosed. If the written consent uses a general designation, it must include a statement that the patient confirms his/her understanding that they are entitled to a list of disclosures.

The “Amount and Kind” section now requires an explicit description of the substance use disorder-related information to be disclosed to ensure that patients understand the information they are disclosing and to allow the disclosing program or other entity to comply with the request. Descriptions such as “all my substance use disorder information” or “none of my substance use disorder information” are not prohibited as long as more specific, granular options are also included. Part 2 programs and lawful holders of patient information need to take into consideration the patient’s reading level standards and the program’s use of plain language to communicate with the patient.

Qualified service organization

The final rule revised the definition of a QSO, which generally means an individual or entity that provides a service to a Part 2 program consistent with the terms of a qualified service organization agreement (QSOA). The revised definition adds “population health management” to the list of services that a QSO may provide to a Part 2 program. It also substituted the term “medical staffing” for the term “medical services” within the list of services provided by a QSO to clarify that a QSO may provide medical staffing services, such as on-call coverage services. However, the final rule warned that the QSO relationship

cannot be used as a way to avoid obtaining patient consent in order for a Part 2 program to communicate with a patient's primary care physician for the purpose of treatment.

Other lawful holders of patient identifying information

The final rule, in revisions to § 2.12, clarifies that Part 2 restrictions on disclosures apply to individuals or entities who received patient records from "other lawful holder[s] of patient identifying information." A lawful holder of patient identifying information is an individual or entity "who has received such information as the result of a Part 2-compliant patient consent (with a re-disclosure notice) or as a result of one of the limited exceptions to the consent requirements specified in the regulations and, therefore, is bound by 42 CFR part 2."⁵ Thus, Part 2 restrictions on disclosures apply to individuals or entities who receive patient records directly from a Part 2 program or other lawful holder of patient identifying information and who are notified of the prohibition on re-disclosure.

Medical emergencies

Section 2.51 of Part 2 describes the circumstances in which patient identifying information can be disclosed by a Part 2 program without patient consent in a medical emergency. SAMHSA revised the medical emergency exception to allow any healthcare provider who is treating the patient for a medical emergency to make the determination that a bona fide medical emergency exists when a patient's prior informed consent cannot be obtained. A patient's inability to give prior informed consent refers only to a patient who is incapable of giving consent, and not a patient who is capable but refuses to give consent.

Research

The final rule substantially revised § 2.52, which permits data protected by Part 2 to be disclosed to qualified personnel for conducting scientific research if the researcher documents that it satisfies certain requirements for data protection. Researchers using patient identifying information obtained under this section are bound by Part 2, and they are required to resist any efforts to obtain access to patient records in judicial proceedings except as permitted by Part 2. The information may not be re-disclosed except back to the individual or entity from which it was obtained. Researchers additionally may include Part 2 data in research reports only in aggregate form that has been rendered non-identifiable. Information must be maintained and destroyed in accordance with the security policies and procedures in the revised § 2.16, and must also retain records in compliance with any applicable laws. The final rule enables researchers who hold Part 2 data to obtain linkages to other datasets, provided that appropriate safeguards are in place. Data repositories are fully bound by Part 2 upon receipt of the patient identifying data. After providing the researcher with the linked data, the repository must destroy or delete the linked data from its records in accordance with Part 2 specifications.

Modifications to become more like HIPAA

One of the recurring themes in the preamble to the final rule was the desire that SAMHSA align Part 2 with the standards of HIPAA.⁶ SAMHSA stated its intent to do so where the governing statute would permit it. For example, it clarified that the definition of "patient identifying information" was intended to incorporate the patient identifiers listed in the HIPAA Privacy Rule. The final rule tailored

the language of the revised § 2.16 to require policies and procedures for electronic records that closely align with the HIPAA Security Rule. However, SAMHSA emphasized that Part 2 and HIPAA are separate and distinct statutory schemes and that Part 2 provides more stringent protections than HIPAA. Consequently, SAMHSA stated it was ultimately constrained by the language and the purpose of Part 2's authorizing statute.

Supplemental Notice of Proposed Rulemaking

In the preamble to the final rule, SAMHSA announced that it was issuing a Supplemental Notice of Proposed Rulemaking (SNPRM), which was published concurrently with the final rule.⁷ SAMHSA observed there were varying interpretations about the restrictions placed on lawful holders and their contractors and subcontractors in the use and disclosure of Part 2-covered data to carry out payment, healthcare operations, and other healthcare-related activities. The SNPRM sought further comment on three proposed revisions to provide clarification. The first proposed revision was to consider whether an abbreviated notice of the prohibition on re-disclosure under § 2.32 would be appropriate in certain circumstances. The second proposal was to revise § 2.33 to list specific types of activities for which a lawful holder of Part 2 information would be allowed to further disclose the minimum information necessary to carry out specific "payment" and "healthcare operations" that are similar to HIPAA Privacy Rule's definition of these terms. The third proposal would further amend § 2.53, which addresses disclosures without patient consent for audit and evaluation purposes, to allow disclosure of patient identifying information to contractors, subcontractors, and legal representatives

conducting audit and evaluation activities. On January 2, 2018, just as this article went to print, SAMHSA announced publication of this final rule.

Compliance takeaways

Some stakeholders have argued the final rule did not go far enough to modernize Part 2's disclosure and consent mechanisms, to align them with HIPAA, or to facilitate the electronic exchange of substance use disorder treatment records. Other stakeholders expressed concern that the final rule will compromise the underlying policy reasons behind Part 2. The substance use disorder and behavioral health community will also now review the final rule from SAMHSA arising from the SNPRM regarding the role of contractors and subcontractors in carrying out payment, healthcare operations, and other healthcare-related activities. Whether the final rule goes far enough to modernize Part 2 will be an ongoing debate. In the meantime, Part 2 programs must carefully review the final rule and amend their written policies, procedures, and documentation where necessary. Among other things, consent forms must be reviewed and revised in light of the final rule, policies and procedures that address the security of a Part 2 program's electronic records should be reviewed, and Part 2 programs must implement the new requirements for providing patients with a list of disclosures. 

1. 82 Fed. Reg. 6052 – Confidentiality of Substance Use Disorder Patient Records. January 18, 2017. Available at <http://bit.ly/2BtLxbc>
2. See 52 Fed. Reg. 21796 (June 9, 1987).
3. SAMHSA: "The Confidentiality of Alcohol and Drug Abuse Patient Records Regulation and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs" Available at <http://bit.ly/2Bv3ia7>
4. 81 Fed. Reg. 6988 – Confidentiality of Substance Use Disorder Patient Records, proposed rule. February 9, 2016. Available at <http://bit.ly/2DoWuZ7>
5. 81 Fed. Reg. 6996-6997 – Qualified Service Organization. February 9, 2016. Available at <http://bit.ly/2DoWuZ7>
6. Ibid, Ref #1
7. 82 Fed. Reg. 5485 - Confidentiality of Substance Use Disorder Patient Records, Supplemental notice of proposed rulemaking. January 18, 2017. Available at <http://bit.ly/2Biu3dN>