PROPOSED UPDATES TO 42 C.F.R. PART 2: SUBSTANCE USE DISORDER PRIVACY RULE

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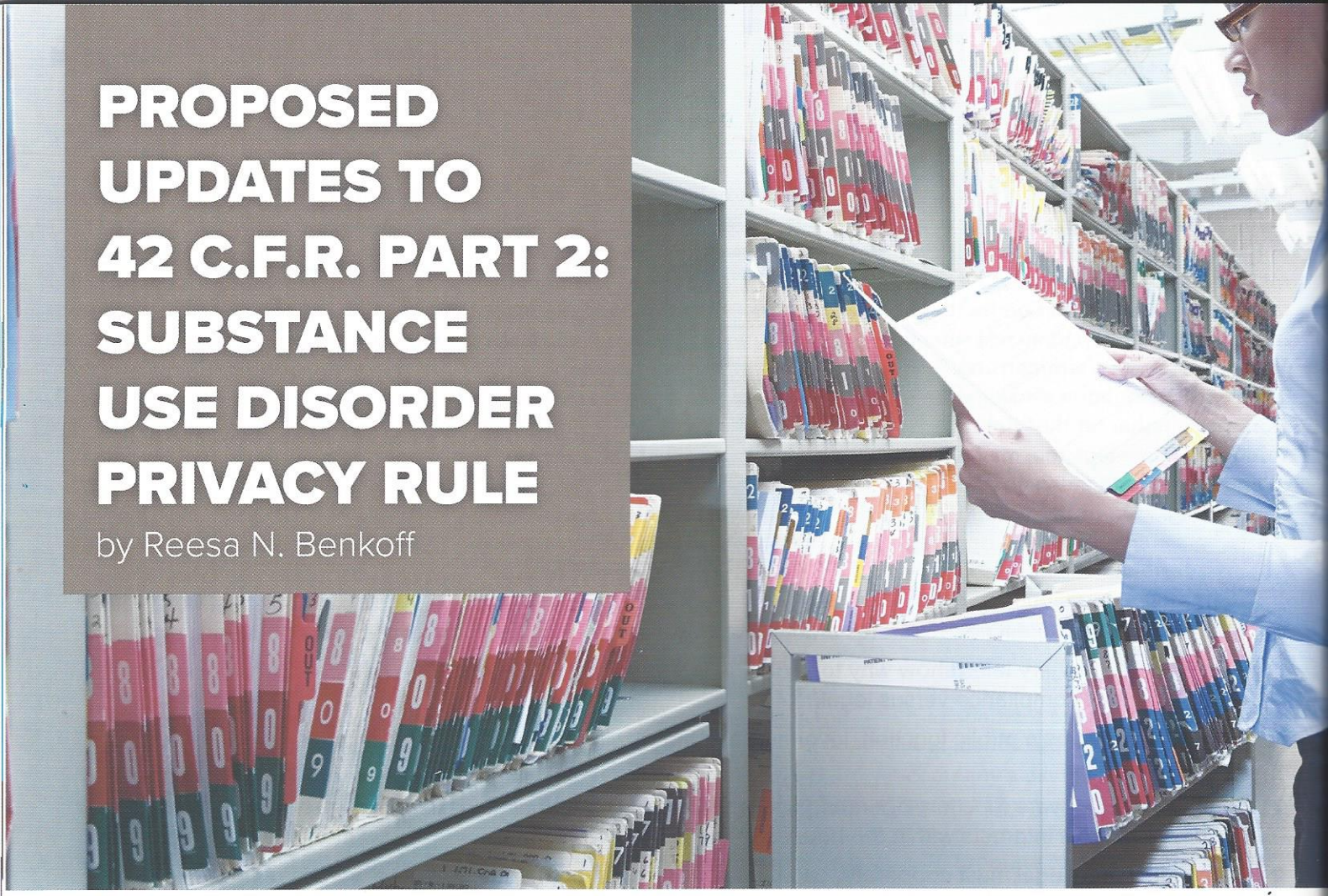

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On August 22, 2019, the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Department of Health and Human Services (HHS) announced proposed changes to the Confidentiality of Substance Abuse Disorder Patient Records regulations, set forth in 42 C.F.R. § 2 (Part 2). Part 2 protects, and prevents access to, patient records created by federally assisted substance abuse disorder (SUD) treatment programs. SUD is a defined term under Part 2, and includes cognitive, behavioral, and physiological symptoms indicating that an individual continues using a substance despite significant substance-related problems, such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. SUD does not include tobacco or caffeine use.[1] Notably, Part 2 is limited in scope, because it applies only to certain programs that treat SUD and receive federal assistance, as such terms are defined within Part 2.

Legislative history

Initially, Part 2 was designed to protect SUD patient records so that patients would not be deterred from seeking SUD treatment. Specifically, Part 2's regulations specify that their intent is to ensure that a patient receiving SUD treatment in a program that is subject to Part 2 is not more vulnerable by virtue of the availability of their patient record than an individual with a SUD who does not seek treatment.[2] For that reason, Part 2 is more restrictive with regard to the disclosure of patient records than HIPAA and general state privacy laws.

However, Part 2 is outdated and creates barriers to treatment and coordination of care amidst the recent opioid crisis. According to HHS's press release, the proposed rule

supports coordinated care among providers who treat SUD, while still maintaining privacy for patients who seek SUD treatment.[3] In addition, the proposed modifications are designed to clarify Part 2's protections and applicability in a manner intended to ensure that providers are not discouraged from treating SUD patients on account of what has historically been viewed as Part 2's onerous regulatory requirements.[4] Specifically, HHS states that: "the proposed rule is the first of four regulations that have been identified in HHS's *Regulatory Sprint to Coordinated Care* that seeks to promote value-based outcomes for patients by examining federal regulations that impede coordinated care among health providers."[5]

In sum, the proposed rule seeks to balance the need to both coordinate care among providers that treat SUD and maintain privacy for patients seeking such treatment. This article categorizes the types of changes sought by the proposed rule into the following broad categories: (1) changes intended to decrease the burden on patients, (2) changes intended to facilitate the coordination of care among providers who treat patients with SUD, (3) changes related to the use of SUD patient treatment records for research purposes, (4) changes intended to resolve existing ambiguities within Part 2, and (5) changes intended to provide further clarity with regard to Part 2 requirements. Interested parties were permitted to submit comments regarding the proposed rule to SAMHSA by October 25, 2019.[6]

Changes intended to decrease burden on patients

First, the proposed rule includes provisions that are intended to decrease the burden on patients created by Part 2's onerous confidentiality rules. Specifically, the proposed rule would allow patients to consent to the disclosure of their Part 2 treatment record to a wide range of entities that do not have a treatment relationship with the patient without being required to name the specific individual who will receive the record on behalf of the entity, which Part 2 currently requires of such consents. Examples of these entities would include, without limitation, the Social Security Administration, halfway houses, and sober living programs.

The proposed rule would also expand the definition of a "bona fide medical emergency" to allow a Part 2 program to disclose the patient's treatment record to another Part 2 program without the patient's consent during a state- or federally declared natural or major disaster (e.g., hurricane) to ensure that the patient can continue to receive ongoing SUD treatment without interruption during the disaster, assuming that the patient's consent cannot otherwise be easily obtained.[7]

Changes intended to facilitate coordination of care

As described by HHS in its press release and publications relating to the proposed rule, one key purpose of the proposed rule is to facilitate the coordination of care between Part 2 providers and non-Part 2 providers. One manner in which the proposed rule seeks to facilitate such coordination is by clarifying that treatment records created by non-Part 2 providers that are derived from their own patient encounters will not be subject to Part 2 even when those records involve SUD, unless those records incorporate SUD records received from a Part 2 program. Consequently, the proposed rule provides means by which a non-Part 2 provider can segment or otherwise hold apart the SUD records it receives from a Part 2 provider to ensure that new records created by the non-Part 2 provider will not become subject to Part 2.[8] The proposed rule explains that segregation of the Part 2 records would allow the recipient to identify and track the Part 2 records, which require heightened protection, while keeping them separate from other paper records or records within an electronic medical record system that are not subject to Part 2.[9] The proposed rule also clarifies that "segregation" does not require the use of a separate server to hold Part 2 electronic records.

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The proposed rule also would permit non-opioid treatment providers that have a treating provider relationship with the patient to access central registries for the purpose of determining whether the patient is already receiving opioid treatment through another program listed in the

registry. This proposed change is intended to assist with care coordination efforts as well as prevent duplicative enrollments and prescriptions for excessive opioids.[10] In addition, the proposed rule would allow Part 2 programs (including opioid treatment providers) to enroll in state prescription drug monitoring programs and report required dispensing data for controlled substances to such programs upon obtaining written consent from the patient.[11]

Changes related to research

The proposed rule also seeks to facilitate disclosures of SUD patient treatment records for research purposes. It intends to do so by better aligning Part 2's research disclosure requirements with those under HIPAA's Privacy Rule[12] and the Common Rule.[13] One way that the proposed rule would facilitate research is by permitting disclosures of Part 2-protected records for research purposes by a HIPAA covered entity or business associate to individuals and organizations who are neither HIPAA covered entities nor subject to the Common Rule, provided that the Part 2-protected data is disclosed in accordance with the HIPAA Privacy Rule.[14] The proposed rule would also permit disclosures for research purposes to members of a HIPAA covered entity's workforce for purposes of employer-sponsored research.[15] Further, the proposed rule contemplates allowing disclosures of Part 2-protected records for research purposes to recipients who are covered by FDA regulations for the protection of human subjects in clinical investigations.[16]

Changes intended to resolve existing ambiguities

HHS and SAMHSA intended that some changes within the proposed rule would resolve ambiguities within Part 2. For example, the proposed rule attempts to resolve ambiguities regarding the scope of permitted disclosures without patient consent for audits and program evaluation purposes by allowing patient-identifying information to be disclosed to government agencies and their contractors, subcontractors, and legal representatives in the course of audits and evaluations mandated by statute or regulation when those activities cannot be carried out using de-identified information.[17]

In addition, the proposed rule attempts to alleviate confusion as to the types of disclosures of SUD treatment records that can be made with the patient's written consent for payment and healthcare operational activities. The proposed rule provides a non-exhaustive list of 17 examples of permitted payment and healthcare operational activities.[18] Notably, the list of 17 examples differs from HIPAA's definition of healthcare operations in that it specifically excludes disclosures made for the purposes of care coordination and case management.

Changes intended to provide clarity

The proposed rule also seeks to provide clarity with respect to certain of its provisions. Specifically, the proposed rule attempts to clarify the time period for the placement of undercover agents and informants within a Part 2 program by specifying a 12-month time period. The proposed rule further provides that the 12-month time period begins when the undercover agent is placed in the Part 2 program or the informant is identified, and that the period can be extended through the placement of a new court order.[19]

Furthermore, the proposed rule explains how Part 2 programs should handle communications made by their employees, volunteers, and trainees who use personal devices, and it states that "records" under Part 2 can be interpreted as including both emails and texts. The proposed rule clarifies Part 2's "sanitization" requirement by providing that the employees, volunteers, and trainees would not need to relinquish, destroy, or otherwise render their personal devices or accounts unusable in the event that the Part 2 program is discontinued. Instead, the proposed rule specifies that, if the email or text contains patient identifying information, the Part 2-protected information should be immediately deleted from the employee's, volunteer's, and/or trainee's personal account or device, after being forwarded to the Part 2 program's authorized communication channel.[20]

What is not affected under the proposed rule

Importantly, the proposed rule does not change Part 2's prohibition on law enforcement's use of SUD patient records in a criminal prosecution against the patient. In addition, the proposed rule will not affect Part 2's restriction on the disclosure of SUD patient records without patient consent, except for those disclosures related to bona fide medical emergencies based upon appropriate court orders for good cause, or made for the purpose of scientific research, audits, and/or program evaluation. The standard for court ordered disclosures of SUD records for the purpose of investigating "an extremely serious crime" will be revised, by dropping the phrase "allegedly committed by the patient" in the proposed rule.[21]

Conclusion

Amid the opioid crisis, Part 2's proposed rule seeks to further balance the need for coordinated care among providers treating patients receiving SUD treatment and the continuing need for heightened patient record privacy to continue to encourage individuals to receive SUD treatment. The proposed rule attempts to do so by modifying Part 2 so that it is less onerous for both healthcare providers and patients. Notably, at the time this went to press, the comment period had expired, but a final rule was not yet published. CT

Endnotes

1. 42 C.F.R. § 2.11.
2. 42 C.F.R. § 2.2(b)(2).
3. HHS.gov, "HHS Proposes 42 CFR Part 2 Reforms to Increase Coordinated Care, Reduce Provider Burden, and Improve Substance Use Disorder Treatment," press release, August 22, 2019, http://bit.ly/36UPr94.
4. HHS.gov, "HHS Proposes 42 CFR Part 2 Reforms."
5. HHS.gov, "HHS Proposes 42 CFR Part 2 Reforms."
6. Confidentiality of Substance Use Disorder Patient Records, 84 Fed. Reg. 44,568 (Aug. 26, 2019).
7. 84 Fed. Reg. 44,568, 44,577.
8. 84 Fed. Reg. 44,568, 44,569.
9. 84 Fed. Reg. 44,568, 44,572.
10. 84 Fed. Reg. 44,568, 44,576.
11. 84 Fed. Reg. 44,568, 44,577.
12. 45 C.F.R. §§ 160, 164.102, 164.500.
13. 45 C.F.R. § 46.
14. 84 Fed. Reg. 44,568, 44,578.
15. 84 Fed. Reg. 44,568, 44,578.
16. 84 Fed. Reg. 44,568, 44,578.
17. 84 Fed. Reg. 44,568, 44,578.
18. 84 Fed. Reg. 44,568, 44,575.
19. 84 Fed. Reg. 44,568, 44,581.
20. 84 Fed. Reg. 44,568, 44,570.
21. HHS.gov, "42 C.F.R. Part 2 Proposed Rule Fact Sheet," press release, August 22, 2019, https://bit.ly/2CjhZLB.

Takeaways

- Proposed changes to 42 C.F.R. § 2 were announced on August 22, 2019.
- Part 2 protects patient records created by federally assisted substance abuse disorder treatment programs.
- The proposed rule seeks to support care coordination among providers while continuing to maintain privacy for patients who seek SUD treatment.
- The proposed rule intends to resolve existing ambiguities within Part 2 and provide further clarity with regard to Part 2 requirements.
- The proposed rule includes provisions that are intended to decrease Part 2's burden on patients.