Netsmart Summary
SAMHSA July 2020 Final Rule Amending 42 CFR Part 2
Final Rule text
SAMHSA news release
SAMHSA fact sheet
Netsmart Comments on SAMHSA Notice of Proposed Rulemaking

Introduction
42 CFR Part 2 substance use treatment record privacy regulations impact Netsmart human services and post-acute clients and those they serve nationwide.

Netsmart is a long-time advocate for updated Part 2 regulations that enable persons to consent to share their substance use disorder (SUD) history with their treating providers, with appropriate privacy safeguards, if they wish to do so. This, combined with the ability for providers to fully utilize that health data for fully-informed diagnosis and treatment, is key to mitigating the impact of co-occurring medical conditions, enhancing patient safety, reducing the stigma associated with SUD and improving the quality of life for millions.

On July 15, 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) published a Final Rule in the Federal Register amending the Confidentiality of SUD Patient Records, 42 CFR Part 2 (Part 2). SAMHSA published the Final Rule as follow up to its Notice of Proposed Rulemaking of Aug. 26, 2019. This Final Rule is effective Aug. 14, 2020.

This summary offers information and insight to providers about the new Final Rule as they update or modify clinical and operational processes for compliance and optimization. *Content is provided for informational purposes only and not intended as legal advice.*

Note: The Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law on March 27, 2020. It amended 42 U.S.C. § 290dd-2, the statute upon which Part 2 is based. While this Final Rule adopts some changes that permit greater flexibility in the sharing of SUD information, it does not include the significant changes that more closely align Part 2 with the federal Health Insurance Portability and Accountability Act (HIPAA) as set forth under the CARES Act. SAMHSA has stated that the CARES Act amendments to Part 2 cannot be made effective prior to March 27, 2021, and they are required to issue a new Final Rule specific to that statute.

Several highlights of the Final Rule include:

- Retains the foundation for confidentiality protection of SUD patient records created by federally-assisted SUD treatment programs

- Adds care coordination and/or case management services to the list of payment and healthcare operations activities for which recipients may redisclose Part 2 records without patient consent. Netsmart advocated for this change it its comment filing to the SAMHSA Notice of Proposed Rulemaking in August 2019. See #5 below for more details
- Makes changes to facilitate the disclosure of records from Part 2 programs to non-Part 2 providers for treatment purposes, while allowing non-Part 2 providers to engage in their own clinical encounters and record-keeping knowing that those activities will not be subject to Part 2
- Offers revised guidance regarding Part 2 consent requirements in order to more explicitly allow patients to consent to disclosure of their records for the purpose of care coordination

Summary of Final Rule amendments
The Final Rule contains the following substantive revisions:

- Definitions (§ 2.11) revises the definition of "Records" to create an exception so that information communicated orally by a Part 2 program to a non-Part 2 provider for treatment purposes with consent does not become a "record" subject to Part 2 merely because it is reduced to writing by that non-Part 2 provider

- Applicability (§ 2.12) now provides that the recording of information about a SUD and its treatment by a non-Part 2 provider does not, by itself, render a medical record subject to Part 2, provided that the non-Part 2 provider segregates any specific SUD records that it receives

- Consent requirements (§ 2.31) Amendments to Part 2 by SAMHSA in January 2017 allow a patient consent for the release of SUD treatment information to be executed to an intermediary, such as a Health Information Exchange (HIE), Accountable Care Organization (ACO), Health Home or other care coordination entity whose members have a treating provider relationship with a patient. Netsmart advocated strongly for that change, which enabled more fully-informed diagnosis and treatment in these value-added care settings. The new Final Rule modifies Part 2 to permit patients to consent to the disclosure of their information to a wide range of entities for non-treatment purposes (for example, to the Social Security Administration when required).

- Prohibition on redisclosure (§ 2.32) revises the notices on prohibition on redisclosure to clarify that non-Part 2 providers do not need to redact information in their or another non-Part 2 record (for example, a record received from another non-Part 2 provider), and confirms that redisclosure is permitted if expressly granted by written consent of the patient or permitted under Part 2

- Disclosures permitted with written consent (§ 2.33) expressly allows disclosure to specified entities and individuals for 18 types of payment and healthcare operational activities, including the addition of disclosures for the purpose of care coordination and case management

- Disclosures to prevent multiple enrollments (§ 2.34) now permits non-opioid treatment providers with a treating provider relationship to access central registries (not including PDMPs) to prevent duplicate program enrollment and prescriptions

- Disclosures to Prescription Drug Monitoring Programs (§ 2.36) creates new permission for opioid treatment programs (OTPs) to disclose dispensing and prescribing data, as required by applicable state law, to prescription drug monitoring programs (PDMPs), subject to patient consent

- Medical emergencies (§ 2.51) authorizes disclosure of information to another Part 2 program or other SUD treatment provider during state or federally-declared natural and major disasters

- Research (§ 2.52) permits research disclosures of Part 2 patient data by a HIPAA covered entity to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule, the baseline standard of ethics to which any government-funded research in the U.S. is held. The Final Rule also now permits research disclosures to recipients who are covered by Food and Drug Administration (FDA) regulations

- Audit and evaluation (§ 2.53) clarifies that federal, state and local governmental agencies and third-party payers may conduct audits and evaluations to identify actions necessary to improve care; audits and evaluations may include medical necessity and utilization reviews; and that auditors may include quality assurance organizations as well as entities with direct administrative control over a Part 2 program or a lawful holder. The Final Rule also updates language related to quality improvement organizations (QIOs), and allows for patient identifying information to be disclosed to federal, state or local government agencies, and to their contractors, subcontractors and legal representatives for audits and evaluations required by statute or regulation

- Orders authorizing use of undercover agents and informants (§ 2.67) amends the period for court-ordered placement of an undercover agent and informant within a Part 2 program to 12 months, starting when an undercover agent or informant is placed in the Part 2 program

Guidance on use of personal electronic devices and accounts

SAMHSA also chose to adopt its proposed guidance on the use of personal electronic devices and how to appropriately deal with Part 2 information on such devices. Under the Final Rule, if a patient contacts a Part 2 program staff member through an employee's (or volunteer's or trainee's) personal email or cell phone account that the staff member does not use in the regular course of business, the staff member should immediately delete the information and only respond via an authorized channel provided by the Part 2 program, unless responding directly from the staff member's account is required in order to protect the best interest of the patient. If the email or text contains patient identifying information, the staff member should forward this information to such authorized channel and then delete the email or text from any personal account.

Analysis of key changes to Part 2 regulations
Here are more details about the key amendments to Part 2 made in the Final Rule.

1. Definition of "Records".

Section 2.11 has been revised to add a limited exception to the definition of "records." Under the Final Rule, a non-Part 2 provider who **orally** receives information from a Part 2 program may subsequently interact with the patient and record the SUD information received from the Part 2 program or the patient into his or her own records, without those records becoming covered by Part 2. SAMHSA stated in the preamble to the Final Rule that "[n]either the enabling statute, nor older versions of the [P]art 2 regulations going back to 1987, ever intended the outcome that an oral communication made by a [P]art 2 program to a non-[P]art 2 provider, subject to patient consent, would make all subsequent clinical recordkeeping by the non-[P]art 2 provider subject to the requirements of [P]art 2." SAMHSA did not, however, explain its rationale for turning a Part 2 record into a non-Part 2 record simply because it was conveyed orally.

Some commenters to the Notice of Proposed Rulemaking expressed concern that creating this oral communication exception would result in an over-reliance upon oral rather than electronic communication, resulting in a reduction in the quality of the data being shared. SAMHSA replied that it believes the change will have the opposite effect, by making it clearer how a non-Part-2 provider can receive and segregate an electronic or paper record from a Part 2 program, without incurring the risk that any patient records directly created by the non-Part-2 program will then become covered by Part 2. However, SAMHSA did not address the legal and compliance privacy concerns related to permitting Part 2 program staff to communicate with other health care providers orally with the potential for misunderstanding or inaccurate transcription of oral communications. In that situation, the Part 2 program and the provider would have to establish whether the oral communication was accurate or not and likely rely upon a written or electronic record as proof.

SAMHSA concludes that only a portion of the record may be orally transmitted and incorporated into the provider's record. The revised definition in the Final Rule will not permit a non-Part 2 provider to engage in the "wholesale transcription" of a received SUD patient record without their own direct patient encounter and without clinical purpose. As such, only portions of the Part 2 record may be transcribed based upon the oral communication.

2. Applicability of Part 2.

SAMHSA recognized there may be confusion about the application of Part 2 rules to non-Part 2 providers. This has resulted in an increased burden on non-Part 2 providers and the potential for impaired coordination of care for patients.

In response, ***the Final Rule now provides that a non-Part 2 treating provider's act of recording information about a SUD in its own record would not make that record subject to Part 2. SUD records received by the non-Part 2 entity from a Part 2 program would remain subject to Part 2 restrictions on redisclosure.*** SAMHSA clarified that Part 2 only applies to SUD patient records "originating" with Part 2 providers. Such Part 2 originating records are subject to Part 2 as they move downstream among recipients.

However, the records created by the non-Part 2 provider in its direct patient encounters would not be subject to Part 2, unless the records received from the Part 2 program are incorporated into the provider's records. The Part 2 program records could be segmented or segregated from the non-Part 2 provider records to avoid being incorporated into the provider's record and to ensure compliance. SAMHSA took these steps to balance patient privacy concerns with the need for SUD information by other health care providers.

The Final Rule reflects this balance. It protects the original Part 2 record but the *information* which the non-Part 2 provider records in its own record is not subject to the same restrictions and protections. The original Part 2 record continues to be segmented or segregated from the non-Part 2 provider's own record. However, the revisions do not impose on non-Part 2 entities any new requirement for data segmentation as a practice, nor do they establish any new standards or requirements for electronic health record (EHR) technology. Most notably, SAMHSA confirmed that non-Part 2 providers have no obligation to segment or segregate SUD records received from a Part 2 program.

To further clarify, SAMHSA changed Part 2 in the Final Rule to reflect that the restrictions on disclosure apply to "any records," rather than to "any information, whether recorded or not" and also to clarify that the restrictions on disclosure apply to the recipients "of Part 2-covered records," rather than to the recipients "of information". The purpose of these amendments was to establish that the redisclosure burden for non-Part 2 entities as lawful holders ties specifically to the protected records they receive from a Part 2 program, and not to any other records that the non-Part 2 entity creates by itself, regardless of whether the latter might include some SUD-related content.

These modifications reduce the burden upon non-Part 2 providers and lawful holders. Part 2 programs still must obtain patient consent or a court order to share information or records. However, the revisions do not apply to the direct disclosure made by a third party that is not a provider (such as a health plan) to a non-Part 2 provider. That manner of disclosure is governed by a separate set of requirements, as modified below.

3. Consent requirements.

SAMHSA has learned that some patients with SUDs would like Part 2 programs to disclose records to third parties—other than third party payers—for reasons other than treatment, including eligibility determinations and seeking non-medical services or benefits from governmental and non-governmental entities. SAMHSA used a patient seeking Social Security benefits as an example. The amendments to Part 2 in 2017 permitted the use of a general designation (the name of the specific individual or entity receiving the record did not need to be set forth in the consent, but the recipient must possess a "treating provider relationship" with the patient).Because third parties such as the Social Security Administration do not have a treating provider relationship with the patient, the previous rule limited or prevented the sharing of SUD records and information since in most cases the patient does not know the name of the individual receiving the records.

The new Final Rule modifies Part 2 to permit disclosures pursuant to a consent that includes the name(s) of the individual(s) or the entity(ies) to whom or to which a disclosure is to be made.

4. Prohibition on redisclosure.

SAMHSA received feedback from the provider community that the language of this section in the previous Part 2 regulations had caused downstream, non-Part 2 providers to redact portions of their own files that identify a patient as having a SUD or a history of SUD. In line with the revisions related to records and applicability above, the Final Rule now confirms that a non-Part 2 provider does not need to redact SUD information in its own records to comply with the Part 2 redisclosure prohibition.

Although the Final Rule clarifies the limits of the redisclosure prohibition, it also contains some confusing guidance. In the Preamble to the Final Rule, SAMHSA notes that downstream non-Part 2 recipients do not need to redact SUD information from their records, "provided that any outside patient record previously received from a Part 2 program or other lawful holder is segregated or segmented." However, as set forth in Section 3 of this analysis above, SAMHSA confirmed that non-Part 2 providers have no obligation to segment or segregate SUD records received from a Part 2 program. In order to interpret these provisions to give meaning to each, it must be assumed that while the Final Rule does not obligate non-Part 2 providers to segment or segregate Part 2 SUD records, they must do so if they desire to redisclose any such records and, more importantly, if they seek to disclose their own records containing SUD information.

5. Disclosures permitted with written consent.

SAMHSA varied from the Proposed Rule of August 2019 and added care coordination and case management to its list of payment and healthcare operations "purposes."

As such, a lawful holder (a recipient who legally received the Part 2 records) may redisclose Part 2 records to its contractors, subcontractors, and/or legal representatives for all payment and healthcare operations purposes as defined by HIPAA, including care coordination and case management. The initial disclosure by the Part 2 program to the lawful holder would still require consent.

In its guidance, SAMHSA stated that the long list of permissible healthcare operations and payment purposes could also be referenced as appropriate purposes for which a Part 2 program's Qualified Service Organization (QSO) could use or disclose SUD records without patient consent.

6. Audit and evaluation.

The Final Rule expanded the audit and evaluation section of Part 2 to permit a wide variety of reviews and examinations not previously acknowledged as constituting an audit or an evaluation. It now permits the sharing of SUD records by a Part 2 program or lawful holder to certain third parties without the need for patient consent. The entities that may conduct an audit or evaluation now include:

- Any individual or entity that provides financial assistance to the Part 2 program or other lawful holder
- A third-party payer covering patients in the Part 2 program
- A quality improvement organization performing a QIO review

- The contractors, subcontractors or legal representatives of such individual, entity or quality improvement organization
- An entity with direct administrative control over the Part 2 program or lawful holder

Purposes that are considered audits and evaluations under the Final Rule include:

- Identifying actions the agency or third-party payer entity can take, such as changes in policies or procedure to improve care and outcomes for patients with SUDs who are treated by Part 2 programs; ensure that resources are managed effectively to care for patients; or determine the need for adjustments to payment policies to enhance care or coverage for patients with SUD
- Reviewing appropriateness of medical care, medical necessity and utilization of services
- Activities of accreditation or similar types of organizations focused on quality assurance

Finally, information may be disclosed to federal, state or local government agencies, and the contractors, subcontractors and legal representatives of such agencies, for audits or evaluations mandated by statute or regulation, if those audits or evaluations cannot be carried out using de-identified information.

Netsmart and 42 CFR Part 2
Netsmart solutions and services facilitate provider compliance with 42 CFR Part 2 requirements, including managing consents, establishing provider permissions, controlling the re-disclosure of select types of information and ensuring data (and data exchange) is appropriately encrypted and protected.

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