

Summary of Recently Released Final Rule: 42 C.F.R. Part 2

On July 15, 2020, the Substance Abuse and Mental Health Services Administration (“SAMHSA”) issued a final rule updating the confidentiality requirements for substance use disorder (“SUD”) patient records under 42 C.F.R. Part 2 (“Part 2”).¹ The final rule is effective August 14, 2020.

The Part 2 final rule aims to reduce delays and burdens in care coordination by more closely aligning Part 2 with the HIPAA Privacy Rule, while maintaining certain privacy protections specific to Part 2. The revisions, however, do not alter the basic framework for confidentiality protection of SUD patient records created by federally assisted SUD treatment programs. Part 2, as amended by the Part 2 final rule, continues to restrict the disclosure of SUD treatment records without patient consent, other than as statutorily authorized in the context of a bona fide medical emergency, for the purpose of scientific research, audit, or program evaluation, or based on an appropriate court order. Part 2 also continues to prohibit law enforcement’s use of SUD patient records in criminal prosecutions against patients, absent a court order.

Of particular note, the changes made by this Part 2 final rule are temporary ones. On March 27, 2020, President Trump signed the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) into law (Pub. L. 116-136). Section 3221 of the CARES Act makes significant modifications to the authorizing statute for Part 2, with the aim of aligning the Part 2 laws more strongly with the HIPAA privacy rule. HHS anticipates releasing a new proposed rule within the next 12 months to implement Section 3221 of the CARES Act.² In the meantime, several of the regulatory amendments in the Part 2 final rule will serve as transitional standards, until HHS can promulgate regulations fully conforming to the CARES Act legislation.

The final revisions to the confidentiality requirements under the current Part 2 final regulations are described in detail below.

“Sanitization” of Employee Devices (preamble-only)

- *When a SUD patient sends an incidental message to the personal device of an employee of a Part 2 program, the employee will be able to fulfill the Part 2 requirement for “sanitizing” the device by deleting that message.*

In the proposed rule, SAMHSA recognized that read together, previous §§ 2.11, 2.16, and 2.19 could be interpreted to mean that a Part 2 program employee who received a text or email from a patient on his or her personal phone or device may have to sanitize it (in some cases rendering it unusable) if the Part 2 program is discontinued. Discussion in the preamble of the proposed rule

¹ Confidentiality of Substance Use Disorder Patient Records, 85 Federal Register 42986 (Jul. 15, 2020).

² Section 3221 of the CARES Act directs the Secretary of Health and Human Services to revise the Part 2 regulations such that the amendments would apply to uses and disclosures of SUD information occurring on or after March 27, 2021, the date that is 12 months after the date of enactment of the CARES Act.

aimed to clarify that this interpretation was not the intent of the regulations, and that the patient message could simply be forwarded to an authorized channel and deleted from the personal device.

In the final rule, SAMHSA adopts the proposed rule and clarifies that, if patient contact is made through an employee's personal email or cell phone account which he or she does not use in the regular course of business, the employee should immediately delete this information from his or her personal account and only respond via an authorized channel, unless responding directly from the employee's account is required in order to protect the best interest of the patient. If the email or text contains patient identifying information, the employee can forward this information to such authorized channel and then delete the email or text from any personal account.

Part 2 “Records” and Re-disclosure (§ 2.11 – Definitions; § 2.12 – Applicability; § 2.32 – Prohibition on Re-disclosure)

- *Treatment records created by non-Part 2 providers based on their own patient encounter(s) are explicitly not covered by Part 2, unless any SUD records previously received from a Part 2 program are incorporated into such records. Segmentation or holding a part of any Part 2 patient record previously received can be used to ensure that new records created by non-Part 2 providers will not become subject to Part 2.*

SAMHSA proposed several changes that were intended to work together to facilitate communication and coordination between Part 2 and non-Part 2 providers. Specifically, the proposed rule aimed to:

- Amend the definition of “record” in § 2.11 to explicitly exclude information that is conveyed orally by a Part 2 program to a non-Part 2 provider.
- Add a new subsection (d)(2)(ii) to § 2.12, to clarify that a non-Part 2 treating provider's act of recording information about an SUD and its treatment would not make that record subject to Part 2 requirements, provided that the non-Part 2 provider segregates any specific SUD records received from a Part 2 program (either directly, or through another lawful holder).
- Amend § 2.12(e)(3) to reflect that the restrictions on disclosure apply to the recipients “of Part 2-covered records,” rather than to the recipients “of information.”
- Streamline § 2.32(a)(1) to remove confusingly broad language from the current notice language for disclosure consent forms, and add language to specifically state that only the record from the Part 2 program is subject to the prohibition on re-disclosure.

The final rule adopts these changes as proposed.

Consent Requirements (§ 2.31)

- *A SUD patient may consent to disclosure of the patient's Part 2 treatment records to an entity without naming a specific person as the recipient for the disclosure.*

SAMHSA proposed to amend § 2.31(a)(4)(i) to clarify that patients only need to name the individual or the entity to which their information is to be disclosed, even in the absence of a treating provider relationship. In addition, SAMHSA proposed to amend the newly redesignated § 2.31(a)(4)(ii) to provide that, if the recipient entity is a health information exchange (HIE) or research institution, the consent must also include either: (1) the name of a specific individual to receive the information; or (2) a general designation of a class of participants who have a treating provider relationship (e.g., “all my treating providers”).

The final rule adopts these changes as proposed, and provides further guidance concerning the application of § 2.31 to disclosures for the coordination of care. Specifically, in response to comments requesting that SAMHSA provide more flexibility to facilitate care coordination and case management, SAMHSA states that the change at § 2.31(a)(4)(i) is intended to make it easier for patients to consent to the disclosure of their information for the purposes of care coordination and case management, including to contracted organizations of lawful holders, by naming such organizations on the consent form (instead of having to designate an individual recipient at the organization by name).

Disclosures for Payment and Health Care Operations (§ 2.33)

- *Disclosures for the purpose of “payment and health care operations” are permitted with written consent, in connection with an illustrative list of 18 activities that constitute payment and health care operations now specified under the regulatory provision.*

The Part 2 regulations permit patients to consent to disclosure of SUD treatment records to contractors, subcontractors, and legal representatives for payment or health care operations activities. SAMHSA proposed to codify a list of 17 specific types of permitted payment and health care operations in the regulatory text. The proposed rule noted that this list was illustrative rather than exhaustive, and proposed to add a regulatory provision to the end of the list to permit “other payment/health care operations activities not expressly prohibited.”

The final rule adds a list of 18 activities that qualify as “payment or health care operations activities,” for which providers may disclose Part 2 records after obtaining patient consent. The final rule expressly includes the 17 proposed activities, and adds “care coordination and/or case management services in support of payment or health care operations” to the list of payment and health care operations activities. Further, in order to avoid confusion about the scope of permissible disclosures related to payment or health care operations, SAMSHA deleted the existing regulatory language in § 2.33(b) that states that “[d]isclosures to contractors, subcontractors, and legal representatives to carry out other purposes such as substance use disorder patient diagnosis, treatment, or referral for treatment are not permitted under this section.”

The addition of “care coordination and/or case management services” to § 2.33(b) in the final rule brings Part 2 in further alignment with the HIPAA Privacy Rule, which includes care coordination and case management activities in the definition of health care operations. Previously, Part 2 considered care coordination to be a treatment activity, as opposed to an operational activity, which meant specific authorization was required for disclosure and use of the SUD record. SAMHSA

initially stated in the proposed rule that § 2.33(b) would not cover disclosures for the purpose of care coordination or case management. However, due to the recent CARES Act amendments as well as public comments in response to the proposed rule, SAMHSA is now including care coordination and case management in the illustrative list of payment and health care operations activities for which disclosures may be made under § 2.33(b).

Disclosures to Prevent Multiple Enrollments (§ 2.34)

- *Non-opioid treatment providers (OTPs) and non-central registry treating providers are now eligible to query a central registry, in order to determine whether their patients are already receiving opioid treatment through a member program.*

SAMHSA proposed to expand the scope of § 2.34 to make non-OTP providers that have a treating provider relationship with the patient eligible to query a central registry to determine whether the specific patient is already receiving opioid treatment through a member program to prevent duplicative enrollments and prescriptions for excessive opioids, as well as to prevent any adverse effects that may occur as a result of drug interactions with other needed medications. Specifically, SAMHSA proposed to amend § 2.34(b) to include the use of central registry information to coordinate care with a non-Part 2 program. In addition, SAMHSA proposed to add a new subsection (d) to specifically permit non-member treating providers to access the central registries. The final rule adopts these changes as proposed by SAMHSA.

Disclosures to Prescription Drug Monitoring Programs (§ 2.36)

- *OTPs are permitted to enroll in a state prescription drug monitoring program (PDMP), and permitted to report data into the PDMP when prescribing or dispensing medications on Schedules II to V, consistent with applicable state law.*

SAMHSA proposed adding a new section § 2.36, permitting OTPs and other lawful record holders to report the required data to their respective state PDMPs when dispensing medications. The proposed rule required Part 2 providers to obtain written consent from the patient whose identifying information would be disclosed prior to making such reports. This update was consistent with the proposal under § 2.34 to allow non-OTPs to query central registries to prevent duplicate enrollment.

The final rule adopts these changes as proposed. Section 2.36 creates new permissions allowing OTPs to disclose dispensing and prescribing data, as required by applicable state law, to PDMPs subject to patient consent. Currently, 41 states require physicians to use their state's PDMP to analyze prescription history prior to writing a prescription for opioids or other controlled substances.

Medical Emergencies (§ 2.51)

- *Declared emergencies resulting from natural disasters (e.g., hurricanes) that disrupt treatment facilities and services are considered a “bona fide medical emergency,” for the purpose of disclosing SUD records without patient consent under Part 2.*

SAMHSA proposed to amend § 2.51 to include natural and major disasters within the meaning of “medical emergency” for which there would be an exception to the requirement of consent for disclosure of Part 2 records. While SAMHSA noted that consent should still be obtained if at all feasible, SAMHSA proposed to authorize, under § 2.51(a), a Part 2 program to disclose patient identifying information to medical personnel, without patient consent, as needed in the event of a natural or major disaster to deliver ongoing SUD services to patients in such disasters. Specifically, SAMHSA proposed that this medical emergency exception would apply only when a state or federal authority declared a state of emergency as a result of a disaster and the Part 2 program is closed and unable to provide services or obtain the informed consent of the patient as a result of the disaster, and would immediately be rescinded once the Part 2 program resumed operations. The final rule adopts these changes as proposed by SAMHSA.

Research (§ 2.52)

- *Disclosures for research under Part 2 are permitted by a HIPAA-covered entity or business associate to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule (re: Research on Human Subjects).*

SAMHSA proposed modifying the text of § 2.52(a) to allow research disclosures of Part 2 data from a HIPAA covered entity or business associate to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule (for example, State agencies), provided that any such data would be disclosed in accordance with the HIPAA Privacy Rule at 45 C.F.R. § 164.512(i). SAMHSA also proposed adding § 2.52(a)(1)(iii), in order to clarify that research disclosures may be made to members of the workforce of a HIPAA covered entity for purposes of employer-sponsored research, where that covered entity required all research activities carried out by its workforce to meet the requirements of either the Privacy Rule and/or Common Rule, as applicable.

In response to comments received, SAMHSA finalized this section as proposed in the final rule, except for the proposed change allowing research disclosures to members of the workforce of a HIPAA covered entity. The proposal aimed to clarify that the lawful holder of Part 2 data could disclose the data to a member of the workforce of a HIPAA-covered entity, provided that the research was being conducted at the direction or on behalf of that individual’s employer. However, given concerns raised during the comment process that this revision may permit employers to conduct SUD research on their employees, and potentially lead to employment discrimination for those with SUD, SAMHSA chose not to adopt this aspect of the proposed rule.

Audit and Evaluation (§ 2.53)

- *Clarifies specific situations that fall within the scope of permissible disclosures for audits and/or program evaluation purposes.*

To clarify which types of program audit and evaluation activities can obtain and use patient identifying information without patient consent, SAMHSA proposed several revisions and additions to the existing regulatory language. SAMHSA in its final rule adopts revisions which clarify that:

- federal, state and local governmental agencies and third-party payers may conduct audits and evaluations to identify needed actions at the agency or payer level to improve care;
- audits and evaluations may include reviews of appropriateness of medical care, medical necessity, and utilization of services; and
- auditors may include quality assurance organizations as well as entities with direct administrative control over a Part 2 program or lawful holder.

Section 2.53 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 audit and evaluations required by statute or regulation.

In response to comments received related to § 2.53(c)(1), SAMHSA, in its final rule eliminated the expectation that certain audits and evaluations conducted by government agencies and third-party payers need to be conducted “periodically”. In doing so, SAMHSA’s final rule notes that determinations about how often information is disclosed for audits and evaluations of this nature are best left to stakeholders with first-hand knowledge of each specific situation. The final version of § 2.53(c)(1) also makes minor changes to the language in (c)(1)(i)-(iii) to clarify SAMHSA’s intent that revisions are intended to help enhance patient care and coverage.

Confidential Communications (§ 2.63)

- *If finalized, will remove the requirement for a crime to be alleged to have been committed by the patient for court-authorized disclosures.*

SAMHSA proposed to amend the Part 2 regulations to provide that a court could authorize disclosure of confidential communications without patient consent when the disclosure was necessary in connection with investigation or prosecution of an “extremely serious” crime, even if the extremely serious crime was not alleged to have been committed by the patient. SAMHSA proposed to remove this requirement for the suspected crime to be alleged to have been committed by the patient, thereby reverting back to the regulatory language that was in place from 1987 to 2017.

SAMHSA has not yet finalized its proposed changes to § 2.63. However, we expect that changes to § 2.63 may be included in a separate final rule.

Use of Undercover Agents (§ 2.67)

- *Court-ordered placement of an undercover agent or informant within a Part 2 program is extended to a period of 12 months, and courts are authorized to further extend the period of placement through a new court order.*

SAMHSA proposed to amend § 2.67(d)(2) to extend the period for court-ordered placement of an undercover agent or informant to 12 months, while authorizing courts to further extend a period of placement through a new court order. In addition, SAMHSA proposed to amend § 2.67(d)(2), to clarify that the proposed 12-month time period starts when an undercover agent is placed, or an informant is identified, in the Part 2 program. The final rule adopts these changes as proposed by SAMHSA.

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