Confidentiality of Substance Use Disorder Patient Records
Notice of Proposed Rulemaking
[SAMHSA-4162-20; RIN: 0930-AA32]

Summary of Proposed Rule

On August 26, 2019, the Substance Abuse and Mental Health Services Administration (SAMHSA) published in the *Federal Register* (84 FR 44568) a proposed rule amending its Confidentiality of Substance Use Disorder Patient Records regulations to better facilitate the exchange of information for individuals in treatment for substance use disorder (SUD) care.

This summary describes SAMHSA proposals to update and clarify 42 CFR part 2 non-disclosure rules, reduce the burden for certain permitted disclosures, expand on certain permitted disclosures, and make other miscellaneous changes. SAMHSA estimates the costs of the proposed updates to part 2 would be between $9.8 and $10.8 million in each year over the 10-year period of 2019–2028 and would total about $99.5 million in undiscounted 2018 dollars over that period. **Comments on the proposed rule are due by 5 pm, October 25, 2019.**

This proposed rule was published in conjunction with a related proposed rule by the same name but numbered RIN: 0930-AA30. The summary for that proposed rule which would clarify one of the conditions under which a court may authorize disclosure of confidential communications made by a patient to a part 2 program (i.e., a federally assisted program for the diagnosis, treatment, or referral for treatment for a substance use disorder) is included as an appendix to this document. **Comments for that proposed rule must be received by 5pm, September 25, 2019.**

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I. Background and Overview of the Proposed Regulations

Existing regulations at 42 CFR part 2 implement section 543 of the Public Health Service Act (42 U.S. Code 290dd-2). They are intended to ensure the confidentiality of patient records for people treated for SUD. There were initially established at a time where there were not privacy and data security standards and were necessary to prevent people with SUD from encountering discrimination or other negative consequences if their treatment information were to be improperly disclosed. The purpose of the rules is to ensure that people receiving treatment for SUD "are not made more vulnerable to investigation or prosecution because of their association with a treatment program than they would be if they had not sought treatment" (48 FR 38763.)

SAMHSA first finalized the regulations in 1975 and updated them in 1987 (52 FR 21796), 1995 (60 FR 22296), 2017 (82 FR 6052) and 2018 (83 FR 239). The 2017 updates were intended to reflect the development of integrated health care models and the growing use of electronic patient information and exchange of information. The objective of the 2018 updates was to provide greater clarity regarding payment, health care operations, and audit or evaluation-related disclosures.

In both the 2017 and 2018 final rules, SAMHSA solicited additional recommendations to better address information sharing within the complexities of health IT, patient privacy, and interoperability. SAMHSA is proposing a number of changes including those to improve information sharing among health care providers of people with SUD that are particularly important to improve coordination of care for people impacted by the opioid crises.

The proposed changes would:

- Clarify that the recording of information by a non-part 2 entity about a patient treated for SUD by an entity operating a part 2 program (hereinafter referred to as a "part 2 entity") does not, by itself, render a medical record subject to part 2 rules provided that the non-part 2 entity segregates SUD records received from a part 2 program. Changes are proposed to the definition of "records" to add additional clarity and to support the proposed changes.
- Permit non-opioid treatment providers access to central registries and to permit opioid treatment programs (OTPs) to disclose dispensing and prescribing data to prescription drug monitoring programs (PDMPs) subject to patient consent. These changes, according to SAMHSA, would limit negative drug interactions and other potentially life-threatening consequences of poor coordination of drugs prescribed to those individuals with those dispensed by OTPs.
- Allow patients to consent to disclosing part 2 treatment information for a wide range of activities without having to name each specific individual receiving that information.
- Allow disclosure of patient information to another part 2 program or SUD treatment provider during disasters without patient consent.
- Specify in regulatory text a list of examples of payment and health care operational activities for which disclosure is permitted to address stakeholder feedback that the existing rules have been confusing on these activities.
- Make amendments to audit and evaluation rules to resolve confusion about disclosures to and from governmental agencies and third-party payers among other clarifications.

- Extend the period of time permitted for placement of undercover agents and informants to 12 months.

Guidance on Use of Personal Devices. In addition to those regulatory proposals, SAMHSA provides guidance in the preamble on how employees, volunteers, and trainees of part 2 facilities should handle communications using personal devices and accounts. The guidance provides that when an employee (or volunteer) makes contact with a patient through personal email or cell phone account, the employee should immediately delete this information from his or her personal account and only respond via authorized channels provided by the part 2 program unless responding directly to the patient is in the patient's best interests. This clarification is intended to mean that provisions in existing 42 CFR part 2 requiring security standards that include "sanitizing" all patient identifying information to render it non-retrievable do not apply to the personal devices or email of personnel who do not use those devices in the regular course of business.

II. Provisions of the Proposed Rule

A. Applicability of Part 2 Rules to Non-Part 2 Providers (§2.12)

SAMHSA proposes changes to the applicability provisions of §2.12 to clarify that the records of non-part 2 entities are not covered by Part 2 restrictions simply because they describe information about a patient's SUD treatment and status. It describes the history of the part 2 restrictions and the need for additional clarity within the provider community about which information collected by non-part 2 entities is covered by the part 2 restrictions.

Part 2 rules, as originally established, restricted the applicability of its disclosure rules only to information obtained by a federally assisted alcohol or drug abuse programs. This limited applicability to only those specialized programs was intended to limit the economic impact of the restrictions for facilities that only provided SUD treatment incident to other types of more general medical care.

In the 2017 final rule, however, changes were made to extend the disclosure restrictions to individuals or entities who receive records from a part 2 program or from another lawful holder. The changes were intended to ensure that records initially created by a part 2 program would be protected throughout a chain of subsequent re-disclosures even if the re-disclosure is to a recipient that is not a part 2 program.

Since the 2017 changes, there has been confusion about whether they effectively make all records of non-part 2 entities or providers (for example primary care providers) subject to part 2 restrictions when the records include information about a patient's SUD treatment and status. SAMHSA states that clarifying that records of non-part 2 entities are not covered by the part 2 rules is increasingly important as the opioid epidemic is increasing the need for individuals with SUD to receive coordinated care from part 2 providers as well as other types of providers and entities.

To confirm that the independent record-keeping of a non-part 2 provider is not subject to part 2 limitations, SAMHSA proposes to add new subsection (d)(2)(ii) to §2.12 (which describes the applicability of the part 2 rules). The new subsection would state that a non-part 2 treating provider may record information about a SUD and its treatment that identifies a patient, and this would not constitute a record that has been re-disclosed under part 2 as long as any part 2 records are segregated from the non-part 2 provider's records.

SAMHSA notes that segregating those records could be straightforward when the part 2 records are paper records or email attachments. Segregating electronic records could be accomplished by use of a Data Segmentation for Privacy (DS4P) compliant EHR platform.

Other conforming changes are proposed as well.

- SAMHSA would modify the definition of "records" to add to the existing definition that information conveyed orally by a part 2 program to a non-part 2 provider for treatment purposes with the consent of the patient does not, if then written down, become a record subject to part 2 rules, and that other records transmitted from a part 2 program to a non-part 2 provider are not subject to part 2 rules as long as they are segregated.
- In several places in §2.12, SAMHSA proposes to replace the use of the term "information" with the term "records." This is to increase clarity and also to address questions from stakeholders about what is meant when rules apply to "information, whether recorded or not." Stakeholders have expressed confusion about what exactly is non-recorded information in this context.
- Under existing provisions on re-disclosure of part 2 information (n §2.32) a notice is required to be provided to an entity receiving part 2 information which identifies a patient. The notice is to inform the recipient that the information is subject to the prohibition on re-disclosure and is protected under part 2. SAMHSA reacts to concerns that this notice is causing those entities or providers to manually redact portions of their data files regarding part 2 patients. SAMHSA proposes to amend §2.32 to clarify that the recording of information about a SUD and its treatment by a non-part 2 entity is permitted and does not constitute records that have been redisclosed under part 2 (provided that records received from a part 2 program are segregated).

B. Consent Requirements (§2.31)

Existing rules permit patients to consent to the sharing of their part 2 protected information. The rules describe the elements that must be included in a written consent for sharing such information in order to ensure that the patient is fully informed and their confidentiality is fully protected. The written consent requires that such information be disclosed to a named individual. This framework, SAMHSA points out, was intended to ensure the sharing of information is only with individuals with a need to know.

SAMHSA has since learned that these rules have impeded individuals from seeking certain types of non-medical services or benefits from governmental and non-governmental entities – such as Social Security benefits and sober living or halfway house programs – because the information cannot be shared with an entity when a patient does not have a named individual as the recipient. For example, if a patient wants a part 2 program to disclose impairment information to the Social

Security Administration for a determination of benefits, he is unable to do so because he cannot identify a specific individual at the agency to receive that information.

To address this problem, SAMHSA proposes to amend the current §2.31(a)(4)(i) to permit disclosures to an *entity(-ies)* as well as to an individual(s). Proposed §2.31(a)(4)(ii) would, however, retain the existing rule's limitation on using a general designation for sharing information in cases in which a patient does not have a treating provider relationship.

C. Disclosures Permitted with Written Consent (§2.33(b))

Existing rules permit a patient to consent to disclosure of their records for payment and/or health care operations activities. In the preamble of the 2018 final rule, SAMHSA had proposed incorporating into the regulatory text a list of 17 examples of permitted payment and health care operations. Because of the many stakeholder questions and comments about the list, SAMHSA did not finalize the list in the regulatory text but maintained it in the preamble of the final rule. In addition, SAMHSA sought to make it clear that the list was illustrative and not intended to be exhaustive.

At this time, SAMHSA believes incorporating those examples into regulatory text would help to clarify the types of payment and operations circumstances to which §2.33(b) is intended to permit disclosures. It proposes to add the following 17 examples to the end of existing §2.33(b) as well as an additional 18th item intended to re-affirm that the list is not exhaustive:

- Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing and related health care data processing;
- Clinical professional support services (e.g., quality assessment and improvement initiatives; utilization review and management services);
- Patient safety activities;
- Activities pertaining to:
    - The training of student trainees and health care professionals;
    - The assessment of practitioner competencies;
    - The assessment of provider and/or health plan performance; and/or
    - Training of non-health care professionals;
- Accreditation, certification, licensing, or credentialing activities;
- Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and/or ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care;
- Third-party liability coverage;
- Activities related to addressing fraud, waste and/or abuse;
- Conducting or arranging for medical review, legal services, and/or auditing functions;
- Business planning and development, such as conducting cost management and planning-related analyses related to managing and operating, including formulary development and administration, development or improvement of methods of payment or coverage policies;

- Business management and/or general administrative activities, including management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations;
- Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;
- Resolution of internal grievances;
- The sale, transfer, merger, consolidation, or dissolution of an organization;
- Determinations of eligibility or coverage (e.g., coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;
- Risk adjusting amounts due based on enrollee health status and demographic characteristics;
- Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges; and
- Other payment/health care operations activities not expressly prohibited.

SAMHSA states that permitted uses under §2.33(b) are not intended to include care coordination or case management nor disclosures to contractors, subcontractors or legal representatives for those purposes. It points out that this is in contrast to rules under the Health Insurance Portability and Accountability (HIPAA) Privacy Rule under which care management and coordination activities are incorporated in the definition of "health care operations." Disclosures for care management and care coordination purposes are, however, permitted under other provisions of part 2, specifically §2.31 and §2.33. Some of the proposals in this proposed rulemaking are intended to facilitate these types of disclosures.

D. Disclosures to Prevent Multiple Enrollments (§2.34)

Under existing rules, patient records (with consent) may be disclosed to a central registry and to a withdrawal management or maintenance treatment program within 200 miles of a part 2 program. These disclosures are intended to minimize dual enrollments in treatment programs and to minimize adverse drug events when two different programs are prescribing the same, similar, or other drugs that may interact with each other and cause adverse events.

Under existing rules, however, a central registry may only disclose such information when asked by a "member program" about a patient's enrollment in another program. SAMHSA proposes to expand the scope of this permitted disclosure so that non-OTP providers with a treating provider relationship may query a central registry to determine if their patient is already receiving opioid treatment.

E. Disclosures to Prescription Drug Monitoring Programs (PDMPs) (new §2.36)

SAMHSA points out that 41 states and the District of Columbia have established and require the use of PDMPs – an electronic database that collects, analyzes and makes available prescription data on controlled substances prescribed by practitioners and non-hospital pharmacies. Doctors in 41 states are required to use the PDMP to examine the prescription history of a person before writing a prescription for opioids or controlled substances. OTPs, however, are not permitted

under existing rules to submit information about the dispensing of controlled substances to those PDMP.

In light of the public health crises presented by the opioid epidemic, SAMHSA proposes in new §2.36 to permit OTPs to report SUD medications prescribed or dispensed to the applicable state PDMP with the written consent of the patient. It expects that with the addition of the OTP data, fewer adverse events, duplicate or contraindicated prescriptions, overdoses, or other fatal drug interactions would occur.

F. Medical Emergencies (§2.51)

Existing rules at §2.51 permit the disclosure of SUD treatment records without a patient's consent in a "bona fide medical emergency". Although that term is not defined in the rules, it is intended to incorporate an urgent clinical situation that is immediately life threatening, making it infeasible to seek the individual's consent.

SAMHSA proposes to add this section to include natural and major disasters within the meaning of a medical emergency for which disclosure may be necessary without a patient's consent. SAMHSA notes that disasters such as hurricanes and wildfires can interrupt the usual access to services and medications, requiring patients to seek treatment in facilities or with providers who do not have full access to their records. This proposed change would ensure that treatment could continue under such circumstances.

SAMHSA would limit this exception to instances where a state or federal authority has declared a state of emergency and the part 2 program is closed and unable to provide services or obtain the informed consent otherwise necessary.

G. Research (§2.52)

Disclosures without a patient's consent may be made under existing §2.52 under limited circumstances for the purposes of conducting scientific research. The permitted disclosures may only be to HIPAA-covered entities or business associates with documented authorization from the patient (or a waiver thereof) consistent with the HIPAA Privacy Rule (45 CFR §164.512(i)) or to institutions subject to the Common Rule protecting human subjects (45 CFR part 46).

SAMHSA has become aware that certain researchers, such as state agencies, do not fall under either of those permitted disclosures. In order to more closely align with the research disclosures permitted under the HIPAA Privacy Rule and the Common Rule, SAMHSA proposes to modify §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, provided that any such data will be disclosed in accordance with the HIPAA Privacy Rule at 45 CFR 164.512(i). This change would, according to SAMHSA, align the requirements of part 2 with the HIPAA Privacy Rule around the conduct of research on human subjects.

SAMHSA is proposing two additional changes to §2.52(a):

- 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 requires all research activities carried out by its workforce to meet the requirements of either the Privacy Rule and/or Common Rule (new §2.52(a)(1)(iii)); and
- To permit research disclosures to recipients who are covered by FDA regulations for the protection of human subjects in clinical investigations (new § 2.52(a)(1)(iv)).

H. Audit and Evaluation (§2.53)

SAMHSA proposes a number of additions to existing rules related to permitted disclosures for audit and evaluation purposes. Under existing rules, if the requirements in §2.53 are met, information may be disclosed to individuals and entities who perform audits or evaluations on behalf of governmental agencies that provide financial assistance to a part 2 program or have regulatory authority over it; a third-party payer for coverage of part 2 patients, an individual or entity which provides financial assistance to a part 2 program, or a quality improvement organization (QIO) performing utilization or quality control review. Patient identifying information may also be disclosed for Medicare, Medicaid, or CHIP audits or evaluations.

There is, however, continued confusion about the applicability of the audit and evaluation provisions under specific circumstances in part due to the absence of a definition of audit and evaluations. SAMHSA proposes to clarify the uses of patient data for audit and evaluation by making the following changes:

- To clarify that auditors may include a non-part 2 entity that has direct administrative control over the part 2 program.
- To clarify that audits and evaluations permitted under this section include:
    - Activities periodically undertaken by a federal, state, or local governmental agency, or a third-party payer entity to (i) Identify actions the agency or third-party payer entity can make to improve care and outcomes across part 2 programs; (ii) Target limited resources more effectively; or (iii) Determine the need for adjustments to payment policies for the care of patients with SUD; and
    - Reviews of appropriateness of medical care, medical necessity, and utilization of services.
- To clarify that quality assurance entities that conduct audits or evaluations under this section may include accreditation organizations or other similar organizations that are focused on quality assurance. The existing rules specifically permit disclosure to QIOs, but this provision would ensure that other types of entities such as accrediting or certification bodies may use such disclosures as well.
- To ensure that if de-identified data are not available, audits and evaluations that are mandated by statute or regulation have access to patient identifying information.
- To make technical changes aligning language related to quality improvement organizations so that it conforms with current QIO regulations.

I. Orders Authorizing the Use of Undercover Agents and Informants (§2.67)

Under existing rules, undercover agents and informants may be placed in a part 2 program for a total of 6 months. That period may be extended by a court order. SAMHSA has determined that since a typical undercover operation can often last longer than 6 months, it is proposing to extend that period to 12 months. In addition, it would clarify that the 12-month period would begin when an undercover agent is placed or an informant is identified in the part 2 program.

III. Collection of Information Requirements

SAMHSA expects that several provisions would increase information collection burdens for part 2 entities.

- Disclosures to state PDMPs in states in which such disclosures are required could result in a total cost burden $4.1 million including both the costs in year 1 of an initial update of the PDMP database and the costs of annual reporting.
- Additional disclosures may occur during natural and major disasters, for research purposes, and for audits and evaluations. SAMHSA estimates that altogether the additional disclosures could result in a cost burden of $6.58 million.

Together the additional burden estimated as a result of proposals in this rule equal $10.7 million.

IV. Regulatory Impact

SAMHSA estimates the costs of the proposed amendments to 42 CFR part 2 would largely be the collection of information burden as discussed above. Altogether those costs would be between $9.8 and $10.8 million in each year over the 10-year period of 2019–2028 and would total about $99.5 million in undiscounted 2018 dollars over that period. It also provides those 10-year estimates at an annual discount rate of 3% ($85 million) and 7% ($70 million).

APPENDIX
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Notice of Proposed Rulemaking
[SAMHSA–4162–20; RIN: 0930-AA30]

On August 26, 2019, the Substance Abuse and Mental Health Services Administration (SAMHSA) published in the *Federal Register* (84 FR 44566) a proposed rule that would make changes to the Confidentiality of Substance Use Disorder Patient Records regulations to clarify one of the conditions under which a court may authorize disclosure of confidential communications made by a patient to a part 2 program. **Comments must be received by 5pm, September 25, 2019.**

Background

The regulations at 42 CFR 2.63 specify the circumstances under which a court may authorize disclosure of confidential communications made by a patient to a part 2 program (i.e., a federally assisted program for the diagnosis, treatment, or referral for treatment for a substance use disorder (SUD)). One of those circumstances is when the "disclosure is necessary in connection with investigation or prosecution of an extremely serious crime allegedly committed by the patient…" [*emphasis added*]. SAMHSA states that the phrase "allegedly committed by the patient" was erroneously added to the regulation text in the agency's final rule of January 18, 2017 (82 FR 6052).

Proposal

SAMHSA indicates that the addition of the phrase "allegedly committed by the patient" will hinder federal law enforcement efforts. The agency argues that removing this phrase from the text of the regulation would help address the opioid public health emergency by facilitating prompt investigation and prosecution of opioid-related crimes committed by individuals other than patients; the agency specifically mentions "rogue doctors and pill mills that have contributed to the opioid crisis." Removal of the phrase would provide law enforcement agencies with access to records that may be necessary to establish that a part 2 program, or an affiliated medical professional, is trafficking drugs instead of providing appropriate treatment for SUD. The proposed rule is silent on the issue of an effective date which means that the change would be effective on the date of publication of the final rule.

Regulatory Impact

The agency does not believe the proposed change would have any additional impact on part 2 programs. It finds that its proposal has no discernable economic impact, does not alter program budgets or obligations of grant or loan recipients, and raises no novel legal or policy questions. SAMHSA states that the rule would neither impose any costs on state or local governments nor have a significant economic impact on a substantial number of small entities. The change would not result in any new reporting burdens under the Paperwork Reduction Act.