DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 2

[SAMHSA-4162-20]

RIN 0930-AA32

Confidentiality of Substance Use Disorder Patient Records

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice of proposed rulemaking proposes changes to the Confidentiality of Substance Use Disorder Patient Records regulations. These proposals were prompted by the need to continue aligning the regulations with advances in the U.S. health care delivery system, while retaining important privacy protections for individuals seeking treatment for substance use disorders (SUDs). SAMHSA strives to facilitate information exchange for safe and effective substance use disorder care, while addressing the legitimate privacy concerns of patients seeking treatment for a substance use disorder. Within the constraints of the statute, these proposals are also an effort to make the regulations more understandable and less burdensome.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: In commenting, please refer to file code SAMHSA 4162-20. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (to avoid duplication, please submit your comments in only one of the ways listed):

1. Electronically. *Federal eRulemaking Portal.* You may submit comments electronically to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.

2. By regular mail. Written comments mailed by regular mail must be sent to the following address ONLY:

The Substance Abuse and Mental Health Services Administration,

Department of Health and Human Services,

Attention: SAMHSA- Deepa Avula,

5600 Fishers Lane, Room 17E41,

Rockville, MD 20857.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. Written comments sent by express or overnight mail must be sent to the following address ONLY:

The Substance Abuse and Mental Health Services Administration,

Department of Health and Human Services,

Attention: SAMHSA- Deepa Avula,

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4. By hand or courier. Written comments delivered by hand or courier must be delivered to the following address ONLY:

The Substance Abuse and Mental Health Services Administration,

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For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Ms. Deepa Avula, (240) 276-2542

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

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Acronyms

ADAMHA Alcohol, Drug Abuse, and Mental Health Administration

CFR Code of Federal Regulations

DEA Drug Enforcement Agency

DOJ Department of Justice

DS4P Data Segmentation for Privacy

EHR Electronic Health Record

FAX Facsimile

FDA Food and Drug Administration

FEMA Federal Emergency Management Agency

FR Federal Register

HHS Department of Health and Human Services

HIPAA Health Insurance Portability and Accountability Act of 1996

HIE Health Information Exchange

NPRM Notice of Proposed Rulemaking

ONC Office of the National Coordinator for Health Information Technology

OTP Opioid Treatment Program

OUD Opioid Use Disorder

PDMP Prescription Drug Monitoring Program

SAMHSA Substance Abuse and Mental Health Services Administration

SNPRM Supplemental Notice of Proposed Rulemaking

SUD Substance Use Disorder

U.S.C. United States Code

I. Background

The Confidentiality of Substance Use Disorder Patient Records regulations (42 CFR part 2) implement section 543 of the Public Health Service Act, 42 United States Code (U.S.C.) § 290dd-2, as amended by section 131 of the Alcohol, Drug Abuse and Mental Health Administration Reorganization Act (ADAMHA Reorganization Act), Pub. L., 102-321 (July 10, 1992). The regulations were originally issued to prevent access to patient records for the treatment of substance use disorder, in a time when there was not broader privacy and data security standard for health data Under the regulations, a "substance use disorder" is a defined term, which refers to a cluster of 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. For the purposes of part 2, this definition does not include tobacco or caffeine use.

The regulations were first promulgated as a final rule in 1975 (40 FR 27802) and amended thereafter in 1987 (52 FR 21796) and 1995 (60 FR 22296). On February 9, 2016, SAMHSA published a notice of proposed rulemaking (NPRM) (81 FR 6988) (the "2016 proposed rule"), inviting comment on proposals to update the regulations, to reflect the development of integrated health care models and the growing use of electronic platforms to exchange patient information, as well as the breadth of laws and regulatory actions implemented since 1975, that more broadly protect patient data, as patients and as consumers. At the same time, consistent with the statute, we (note that

throughout this proposed rule, "we" refers to SAMHSA) wished to preserve confidentiality protections it establishes for patient identifying information from covered programs because persons with substance use disorders may encounter significant discrimination or experience other negative consequences if their information is improperly disclosed.

In response to public comments, on January 18, 2017, SAMHSA published a final rule (82 FR 6052) (the "2017 final rule"), providing for greater flexibility in disclosing patient identifying information within the health care system, while continuing to protect the confidentiality of substance use disorder patient records. SAMHSA concurrently issued a supplemental notice of proposed rulemaking (SNPRM) (82 FR 5485) (the "2017 proposed rule") to solicit public comment on additional proposals. In response to public comments, SAMHSA subsequently published a final rule on January 3, 2018 (83 FR 239) (the "2018 final rule") that provided greater clarity regarding payment, health care operations, and audit or evaluation-related disclosures, and provided language for an abbreviated prohibition on re-disclosure notice.

In both the 2017 and 2018 final rules, SAMHSA signaled its intent to continue to monitor implementation of 42 CFR part 2, and to explore potential future rulemaking to better address the complexities of health information technology, patient privacy, and interoperability, within the constraints of the statute. The emergence of the opioid crisis, with its catastrophic impact on individuals, families, and caregivers, and corresponding clinical and safety challenges for providers, has highlighted the need for thoughtful updates to 42 CFR part 2. The laws and regulations governing the confidentiality of

substance abuse records were originally written out of concern for the potential for misuse of those records against patients in treatment for a SUD, thereby undermining trust and leading individuals with substance use disorders not to seek treatment. As observed in the 1983 proposed rule, the purpose of 42 CFR part 2 is to ensure that patients receiving treatment for a substance use disorder in a part 2 program "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).

In recent years, the devastating consequences of the opioid crisis have resulted in an unprecedented spike in overdose deaths related to both prescription and illegal opioids including heroin and fentanyl,[1] as well as correspondingly greater pressures on the SUD treatment system, and heightened demand for SUD treatment services. This proposed rule proposes changes to the regulation that SAMHSA believes would better align with the needs of individuals with SUD and of those who treat these patients in need, and help facilitate the provision of well-coordinated care, as while ensuring appropriate confidentiality protection for persons in treatment through part 2 programs.

II. Overview of the Proposed Regulations

Balancing the concerns noted above, SAMHSA proposes several changes to the regulations at 42 CFR part 2 (part 2). First, we propose to amend language throughout the regulation to clarify several aspects of the applicability and disclosure requirements. Specifically, in Section III.B., Applicability, SAMHSA proposes to amend § 2.12 to

[1] Recent statistics published by the Centers for Disease Control and Prevention reflect a spike in the rate of opioid-related overdose deaths in recent years. See https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w.

clearly state in the regulatory text that the recording of information about a SUD and its treatment by a non-part 2 entity does not, by itself, render a medical record subject to the restrictions of 42 CFR part 2, provided that the non-part 2 entity segregates any specific SUD records received from a part 2 program (either directly, or through another lawful holder). SAMHSA believes this proposed language would encourage part 2 programs and non-part 2 providers to deliver better and safer coordinated care, while also protecting the confidentiality of individuals seeking such care. SAMHSA explains this proposal more fully in Section III.B.

In addition, SAMHSA proposes several changes to 42 CFR part 2, consistent with the proposed policy described above. Specifically, in Section III.A., Definitions, we propose to amend and clarify the definition of "Records" in § 2.11, in a manner that aligns with the proposed revision to § 2.12 described above. And in Section III.D., Prohibition on Re-disclosure, SAMHSA proposes to amend the standard written notice in § 2.32, to clarify the disclosure and re-disclosure limits under 42 CFR part 2.

Additionally, SAMHSA seeks to reduce barriers to care coordination for patients with SUD, in Section III.F., Disclosure to Prevent Multiple Enrollments, by proposing to amend § 2.34 to allow non-opioid treatment providers (e.g., non-part 2 providers who nevertheless manage care for patients with SUD from time to time) to access central registries. In Section III.G., Disclosure to Prescription Drug Monitoring Programs, SAMHSA proposes to add new § 2.36 to permit 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. As noted

above, patient safety is of paramount importance, and many drugs prescribed and dispensed by non-OTPs could have life-threatening and even deadly consequences if not properly coordinated with those prescribed and dispensed by OTPs. Therefore, SAMHSA believes it necessary for both OTPs and non-OTPs to report, and to access, prescription drug records in central registries and PDMPs, and to monitor dosing accordingly.

SAMHSA also makes several proposals that specifically decrease burden for patients accessing care, without compromising patient confidentiality. First, in Section III.C., Consent Requirements, SAMHSA proposes to amend § 2.31, to allow patients to consent to the disclosure of their information to a wide range of entities, without naming the specific individual receiving this information on behalf of a given entity; special instructions would apply with respect to consents for disclosure of information to information exchanges and research institutions. We believe this proposal would give patients the ability to apply for and access federal, state, and local resources and benefits more easily, (e.g., social security benefits; local sober living or halfway house programs). Second, in Section III.H., Medical Emergencies, SAMHSA proposes to amend to § 2.51 to allow disclosure of patient information to another part 2 program or other SUD treatment provider during State or Federally declared natural and major disasters. SAMHSA believes this proposal would reduce the burden of disclosure requirements both for patients to receive, and for clinicians to provide, care that may not be otherwise feasible during natural and major disasters, ensuring that patients can continue to receive on-going and appropriate care.

In Section III.E., Disclosures Permitted with Written Consent, SAMHSA proposes amendments to § 2.33 to expressly allow disclosure to specified entities and individuals for 17 types of payment and health care operational activities. Although SAMHSA believes these activities were already permitted by the regulation, we have received feedback from stakeholders that there remains some confusion on these points. Therefore, we believe it necessary to more clearly state this regulatory permission in the regulatory text, to avoid any further confusion. SAMHSA also proposes amendments to § 2.53 (Audit and Evaluation) together with clarifying guidance, under Section III.J. The amendments to § 2.53 would help to resolve confusion about permitted types of disclosures to and from federal, state and local governmental agencies and to and from third-party payers, for the purpose of audit and evaluation, among other changes. They would also allow patient identifying information to be disclosed to federal, state, and local agencies, and the contractors, subcontractors, and legal representatives of such agencies in the course of conducting audits or evaluations mandated by statute or regulation, if those audits or evaluations cannot be carried out using de-identified information. Likewise, in section III.I., Research, SAMHSA proposes to allow 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, for the purpose of conducting scientific research. SAMHSA believes this change will better align the requirements of part 2, the Common Rule, and the Privacy Rule around the conduct of research on human subjects, and will help to streamline duplicative requirements for research disclosures under part 2 and the Privacy Rule in some

instances. SAMHSA is also proposing to amend section § 2.52 (Research) to clarify that research disclosures may be made to members of the workforce of a HIPAA covered entity for purposes of employer-sponsored research, as well as to permit research disclosures to recipients who are covered by FDA regulations for the protection of human subjects in clinical investigations (at 21 CFR Part 50).

In Section III.K., Orders Authorizing Use of Undercover Agents and Informants, SAMHSA proposes to revise our policies in § 2.67 for the placement of undercover agents and informants within a part 2 program, to provide more clarity regarding the permitted time period for placement pursuant to court order.

Finally, SAMHSA provides the following guidance on how employees, volunteers and trainees of part 2 facilities should handle communications using personal devices and accounts, especially in relation to § 2.19 concerning disposition of records by discontinued programs. In § 2.11, the current regulation defines "Records" to include information relating to a patient that could include email and texts. In § 2.19, the regulation codifies the requirements for disposition of records from a discontinued part 2 program. These requirements state that records which are electronic must be "sanitized" within one year of the discontinuation of the part 2 program. This sanitization must render the patient identifying information non-retrievable in accordance with § 2.16 (security for records). Read together, current §§ 2.11, 2.16, and 2.19 could be interpreted to mean that, if an individual working in a part 2 program receives a text or email from a patient on his or her personal phone which he or she does not use in the regular course of their employment in the part 2 program, and this part 2 program is discontinued, the

personal device may need to be sanitized. Depending on the policies and procedures of the part 2 program, this sanitization may render the device no longer useable to that individual. SAMHSA clarifies that this interpretation is not the intent of the regulations.

Although SAMHSA does not encourage patient communication through personal email and cell phones, it recognizes that patients may make contact through the personal devices or accounts of an employee (or volunteer or trainee) of a part 2 program, even if the employee (or volunteer or trainee) does not use such device or account in the regular course of their employment in the part 2 program. In such instances, SAMHSA wishes neither to convey that these devices become part of the part 2 record, nor that, if the part 2 program is discontinued, these devices must be sanitized. Instead, SAMHSA clarifies that, in the case that patient contact is made through an employee's (or volunteer's or trainee's) personal email or cell phone account which he or she does not use in the regular course of business for that part 2 program, the employee should immediately delete this information from his or her personal account and only respond via an authorized channel provided by the part 2 program, 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 should forward this information to such authorized channel and then delete the email or text from any personal account. These authorized channels are then subject to the normal standards of sanitization under §§ 2.16 and 2.19 and any other applicable federal and state laws. SAMHSA believes that this process will both protect the employee's personal property

and the confidentiality of the patient's records if the patient makes such unauthorized contact.

III. Provisions of the Proposed Rule

A. Definitions (§ 2.11)

In the current regulation, "Records" is defined to mean "any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient." In the 2017 final rule, SAMHSA noted that some commenters expressed confusion regarding what is considered unrecorded information (82 FR 6068); it, therefore, added parenthetical examples in an effort to clarify. But with the exception of these parenthetical examples, the basic definition for "records" under part 2 has remained the same since the 1987 final rule.

In a subsequent section of this proposed rule (III.B.) on "Applicability" (at § 2.12), SAMHSA discusses a proposed change to the restriction on disclosures under part 2, which would serve to clarify some record-keeping activities of non-part 2 providers that fall outside the scope of 42 CFR part 2. As explained in section III.B., the proposed change is needed to facilitate communication and coordination between part 2 programs and non-part 2 providers, and to ensure that appropriate communications are not hampered by fear among non-part 2 providers of inadvertently violating part 2, as a result of receiving and reading a protected SUD patient record and then providing care to the patient.

SAMHSA proposes here to make a conforming amendment to the § 2.11 definition of "records," by adding, at the end of the first sentence of the definition, the

phrase, "provided, however, 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 become a record subject to this part in the possession of the non-part 2 provider merely because that information is reduced to writing by that non-part 2 provider. Records otherwise transmitted by a part 2 program to a non-part 2 provider retain their characteristic as a "record" subject to this part in the possession of the non-part 2 provider, but may be segregated by that provider."

The effect of this proposed amendment would be to incorporate a very limited exception to the definition of "records," such that a non-part 2 provider who orally receives a protected SUD record from a part 2 program may subsequently engage in an independent conversation with her patient, informed by her discussion with the part 2 provider, and record SUD information received from the part 2 program or the patient, without fear that her own records thereafter would become covered by part 2. As discussed below in the proposed revisions to the "Applicability" section of part 2 (at § 2.12), the intent of these proposed clarifications is to better facilitate coordination of care between non-part 2 providers and part 2 programs, and to resolve lingering confusion among non-part 2 providers about when and how they can capture SUD patient care information in their own records, without fear of those records being subject to the confidentiality requirements of part 2.

B. Applicability (§ 2.12)

In the 1987 final rule, SAMHSA broadly established that the restrictions on disclosure under 42 CFR part 2 would apply to any alcohol and drug abuse information

obtained by a federally assisted alcohol or drug abuse program. As explained in 1987, by limiting the applicability of 42 CFR part 2 to specialized programs – that is, to those programs that hold themselves out as providing and which actually provide alcohol or drug abuse diagnosis, treatment, and referral for treatment – the aim was to simplify the administration of the regulations, but without significantly affecting the incentive to seek treatment provided by the confidentiality protections. Limiting the applicability of 42 CFR part 2 to specialized programs was intended to lessen the adverse economic impact of the regulations on a substantial number of facilities which provide SUD care only as incident to the provision of general medical care. The exclusion of hospital emergency departments and general medical or surgical wards from coverage was not seen as a significant deterrent to patients seeking assistance for alcohol and drug abuse. SAMHSA's experience in the more than 30 years since 1987 has been consistent with this expectation.

The 2017 final rule elaborated on this policy, by establishing that the disclosure restrictions on SUD patient records would extend to individuals or entities who receive such records either from a part 2 program or from *another lawful holder*. *See* 42 CFR 2.12(d)(2)(i)(C). As explained in the 2017 final rule, 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, or as a result of one of the exceptions to the consent requirements in the statute or implementing regulations (82 FR 6068). Thus, the effect of the 2017 rule was to expand the scope of application for part 2 confidentiality, by ensuring that records initially created by a part 2 program would

remain protected under 42 CFR part 2 throughout a chain of subsequent re-disclosures, even into the hands of a downstream recipient not itself a part 2 program. The reason for the 2017 change was, once again, to avoid any deterrent effect on patients seeking specialized SUD care through part 2 treatment programs, by virtue of the patient records from those programs losing their part 2 confidentiality protection following a disclosure downstream to other "lawful holder" recipients of those records (81 FR 6997).

Although that policy was established in the 2017 final rule, specifically in § 2.12(d)(2)(i)(C), there remains some confusion within the provider community about what information collected by non-part 2 entities is (or is not) covered by the part 2 restrictions on re-disclosure. When SAMHSA expanded the reach of the Applicability provision in 2017, the intent was not to change the policy established in the 1987 rulemaking, nor to make the records of non-part 2 entities (such as some primary care providers) directly subject to 42 CFR part 2, simply because information about SUD status and treatment might be included in those records. Rather, the intent underlying the 2017 provision was to clarify the applicability of 42 CFR part 2 in a targeted manner, so that records initially created under the protection of part 2 would continue to be protected following disclosure to downstream recipients. In doing so, SAMHSA sought to encourage individuals to enter into SUD treatment through part 2 programs, by strengthening the confidentiality protection for records that originate from those programs. Implicit in SAMHSA rulemaking since 1987 has been the pursuit of a balance of policy interests: on the one hand, consistent with the Congressionally stated purpose of the drug abuse confidentiality statute, to encourage entry into SUD treatment by

ensuring that the records of treatment through a part 2 program would not be publicly disclosed, and on the other hand, to reduce the adverse impact of part 2 burdens on general medical care providers and facilities and on patient care.

In the wake of the nation's opioid epidemic and continuing trends related to alcohol use disorder and cannabis use disorder, it has become increasingly important for primary care providers and general medical facilities not covered by 42 CFR part 2 to be able to carry out treatment and health care operations that sometimes involve creating new records that mention SUD status and care. Such records and activities are not covered by 42 CFR part 2. However, coordination of care between part 2 programs and non-part 2 providers would involve the disclosure of SUD records and information by the former to the latter. Under the current 42 CFR part 2 regulation, such disclosures of records by a part 2 program to a non-part 2 provider do not render all subsequent records on SUD caretaking activity undertaken by the non-part 2 provider subject to the part 2 regulation. For example, when a non-part 2 provider is directly treating her own patient, and creates a record based on her own patient contact that includes SUD information, then that record is not covered by part 2.

Nevertheless, SAMHSA recognizes that there may be significant confusion or misunderstanding as to the applicability of part 2 rules to non-part 2 providers. This results in increased burden on non-part 2 providers, and the potential for impaired coordination of care for patients, which could be life threatening, for example, if an affected patient has an opioid use disorder. Although the existing text of 42 CFR § 2.12 (d)(2)(i)(C) on Applicability does not compel these results, SAMHSA's experience in

recent years has demonstrated the need for clearer regulatory language, to better delineate the records of non-part 2 entities which are not covered by the 42 CFR part 2 rules .

Based on the above considerations, SAMHSA proposes to add a new subsection (d)(2)(ii) to § 2.12, to better clarify that a non-part 2 treating provider's act of recording information about a SUD and its treatment would not make that record subject to 42 CFR part 2. SUD records received by that non-part 2 entity from a part 2 program are subject to part 2 restrictions on redisclosure of part 2 information by lawful holders, including redisclosures by non-part 2 providers. However, the records created by the non-part 2 provider in its direct patient encounter(s) would not be subject to part 2, unless the records received from the part 2 program are incorporated into such records. Segregation of any part 2 records previously received from a part 2 program can be used to ensure that new records (e.g., a treatment note based on a direct clinical encounter with the patient) created by non-part 2 providers during their own patient encounters would not become subject to the part 2 rules.

SAMHSA believes that this addition would further clarify the 2017 revisions, by affirming that the independent record-keeping activities of non-part 2-covered entities remain outside the coverage of 42 CFR part 2, despite such providers' (segregated) possession, as lawful holders, of part 2-covered records. The part 2 disclosure restrictions only apply to SUD patient records originating with part 2 providers. Such part 2 originating records are subject to the part 2 limitations on use and disclosure as they move through the hands of other "lawful holders" and part 2 programs. Even where part 2 does not apply to a patient record created by a non-part 2 provider following a direct

patient encounter, that record will nevertheless be subject to the HIPAA Privacy Rule.

One means by which non-part 2 treating providers could benefit from the above proposal would be through the segregated storage of part 2-covered SUD records received from a part 2 program or other lawful holder. In the context of a paper record received from a part 2 program, the proposed requirement could be met by the "segregation" or "holding apart" of these records; in the context of electronic records from a part 2 program, the proposed requirement could be met by logical "segmentation" of the record in the electronic health record (EHR) system in which it is held. As under the current rule, when a non-part 2 entity receives a protected SUD record from a part 2 program or other lawful holder, the received record is subject to the heightened confidentiality requirements under part 2. "Segregating" the received record, whether by segmenting it or otherwise labeling or holding it apart, would allow the recipient entity to identify and keep track of a record that requires heightened protection.

Under both the proposal and the current text of part 2, the lawful holder recipient entity remains subject to part 2 re-disclosure restrictions with regard to the part 2 record, whether or not the recipient entity is able to segregate it. But "segregating" allows the recipient entity both to keep track of the part 2 records, and readily distinguish them from all the other patient records that the entity holds which are not subject to part 2 protection. As mentioned above, "segregating" the part 2 record may involve physically holding apart any part 2-covered records from the recipient's other records, which would be quite feasible in the case of a received paper record or an email attachment containing such data. Alternately, "segregating" can involve electronic solutions, such as segmenting

an electronic SUD patient record received from a part 2 program by use of a Data Segmentation for Privacy (DS4P) compliant EHR platform, in which segmentation is carried out electronically based on the standards of DS4P architecture (discussed further below). Either of these methods for "segregating" part 2 covered records is a satisfactory way for the recipient entity to keep track of them, and to distinguish them from all the other patient records that the entity holds which are not subject to part 2 protection. We note that "segregating" a received part 2 record does not require the use of a separate server for holding the received part 2 records. We do not intend this rule to result in the creation of separate servers or health IT systems for part 2 documents. Our policy is intended to be consistent with existing technical workflows for data aggregation, storage, and exchange.

One concern that this proposal raises is the possibility that a non-part 2 provider might transcribe extensively from a part 2 record without having a clinical purpose for doing so. This, however, is not the intent of the proposal. Briefly, the intent is to allow a non-part 2 provider to receive SUD information about a patient from a part 2 program, and then to engage in a treatment discussion with that patient, informed by that information, and then be able to create her own treatment records including SUD content, without the latter becoming covered by part 2. This level of flexibility is needed in order to improve coordination of care efforts, and to save lives. It is not SAMHSA's intent to encourage a non-part 2 provider to abuse the rules, by transcribing extensively from a conversation with a part 2 program or from a received part 2 record when creating her own records, without having a clinical purpose for doing so.

In the 2017 final rule, SAMHSA responded to several public comments about data segmentation issues connected to 42 CFR part 2. We acknowledged then that although significant challenges exist for data segmentation of SUD records within some current EHR systems, SAMHSA has led the development of use- case discussions related to the technical implementation of the Data Segmentation for Privacy (DS4P) standard and recently contributed to the development of the FHIR implementation guide for Consent2Share.[2] We believe that DS4P and Consent2Share are important tools to advance the needs of part 2 providers and providers across the care continuum. SAMHSA recognizes and encourages the further development of DS4P standards, and the adoption by providers of EHR systems that meet those standards. The current proposal for revising § 2.12 does not, however, impose on non-part 2 entities any new requirement for data segmentation as a practice, nor does it establish any new standards or requirements for EHR technology. SAMHSA considered including, in this proposed rule, the policy option of defining "segmented" and "segmentation" under 42 CFR part 2, in order to offer greater clarity about what these terms mean under the rule. We decided not to do so, however, since a formal definition of segmentation might have unforeseen technical ramifications for EHR and HIE systems implementation in the future. In addition, SAMHSA believes this policy should be flexible, to allow providers with different operational standards and capabilities to implement the policy with regard to segregation or segmentation in the least burdensome way to their practices, while still maintaining confidentiality of patient records subject to part 2. Nevertheless, using health IT to

[2] "Consent2Share FHIR Profile Design.docx" can be accessed at https://gforge.hl7.org/gf/project/cbcc/frs/.

support data segmentation for privacy and consent management is one path that a provider could use to support their effort to meet part 2 requirements including those described in this proposed rule.

In addition to the proposed revision to 42 CFR § 2.12(d) above, SAMHSA proposes conforming changes to the regulatory text of several other sections of 42 CFR § 2.12, to provide further clarification of the applicability of part 2 restrictions on patient records.

In § 2.12(a), SAMHSA proposes to change the text to reflect that the restrictions on disclosure apply to "any records," rather than to "any information, whether recorded or not." We also propose a conforming change to § 2.12(a)(ii), to indicate that the restrictions of this part apply to any records which "contain drug abuse information obtained…" or "contain alcohol abuse information obtained…" Taken together, these changes are congruent with the amendment to § 2.12(d) and help to make it clear that part 2 applies to "records" (as defined under § 2.11).

In § 2.12(e)(3), SAMHSA proposes to change the text to reflect that the restrictions on disclosure apply to the recipients "of part 2-covered records," rather than to the recipients "of information." This proposed change is congruent with the proposed amendment to § 2.12(d) and would help to make explicit that downstream restrictions on re-disclosure by non-Part 2 entities are tied to protected records which originate from a part 2 program in the first instance. SAMHSA believes that this proposed conforming change is important, because it would further establish that the re-disclosure burden for non-part 2 entities ties specifically to the protected records that 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.

In § 2.12(e)(4), SAMHSA likewise proposes a conforming change to the text, by adding language to reflect that a diagnosis prepared by a part 2 program for a patient who is neither treated by nor admitted to that program, nor referred for care elsewhere, is nevertheless covered by the regulations in this part. The proposed change to the regulatory text is for clarity, to ensure that this section could not be misread as applying directly to the activities of a non-part 2 entity or provider.

Similarly, and congruent with the above conforming changes, SAMHSA is also proposing to modify the definition of "Records" in § 2.11 as discussed in Section III.A. above and to modify and streamline the language in § 2.32 as discussed in Section III.D. below. Readers are referred to those sections of the proposed rule for specifics on those proposals and the rationales for such proposed policies.

C. Consent Requirements (§ 2.31)

In the 2017 final rule, SAMHSA made several changes to the consent requirements at § 2.31, to facilitate the sharing of information within the health care context, while ensuring the patient is fully informed and the necessary confidentiality protections are in place. Among those changes, SAMHSA amended the written consent requirements regarding identification of the individuals and entities to whom disclosures of protected information may be made (82 FR 6077). Specifically, SAMHSA adopted a framework for disclosures to entities that made several distinctions between recipients that have a treating provider relationship with the patient, and recipients that do not.

Under the current rules at § 2.31(a)(4), if the recipient entity does not have a treating provider relationship with the patient whose information is being disclosed and is not a third-party payer, such as an entity that facilitates the exchange of health care information or research institutions, the written consent must include the name of the entity and one of the following: "*the name(s) of an individual participant(s); the name(s) of an entity participant(s) that has a treating provider relationship with the patient whose information is being disclosed; or a general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed*." As stated in the 2017 final rule, SAMHSA wants to ensure that patient identifying information is only disclosed to those individuals and entities on the health care team with a need to know this sensitive information (82 FR 6084). SAMHSA, accordingly, limited the ability to use a general designation in the 'to whom' section of the consent requirements to those individuals or entities with a treating provider relationship to the patient at issue.

Since the 2017 final rule was published, SAMHSA has learned that some patients with substance use disorders may want part 2 programs to disclose protected information to entities for reasons including eligibility determinations and seeking non-medical services or benefits from governmental and non-governmental entities (e.g., social security benefits, local sober living or halfway house programs). Because these entities lack a treating provider relationship with the patient, the current rules preclude them from being designated by name to receive the information, unless they are third-party payers,

or the patient knows the identity of the specific individual who would receive the information on behalf of the benefit program or service provider. In addition, many of these entities may not be able to identify a specific employee to receive application information, and instead are likely to encourage patients to contact them or apply online, such that information is submitted to the organization rather than to a specific person. SAMHSA has heard that many patients have encountered frustration and delays in applying for and receiving services and benefits from, and in authorizing part 2 providers to release their information to, entities providing such services and benefits, by virtue of the inability to designate these entities by organization name only on the written consent for disclosure of part 2 information. It is not SAMHSA's intent to limit patients' ability to consent to the disclosure of their own information. We wish, rather, to empower patients to consent to the release and use their health information in whatever way they choose, consistent with statutory and regulatory protections designed to ensure the integrity of the consent process.

Therefore, SAMHSA proposes to amend the current regulations to clarify that patients may consent to disclosures of part 2 information to organizations without a treating provider relationship. We propose to amend § 42 CFR 2.31(a)(4)(i), which currently requires a written consent to include the names of individual(s) to whom a disclosure is to be made. The amendment would insert the words "or the name(s) of the entity(-ies)" to that section, so that a written consent must include the name(s) of the individual(s) or entity(-ies) to whom or to which a disclosure is to be made. SAMHSA believes that this language aligns more closely with the wording of the regulation before

the January 2017 final rule changes and would alleviate problems caused by the inability to designate by name an individual recipient at an entity. For example, if a patient wants a part 2 program to disclose impairment information to the Social Security Administration for a determination of benefits, such patient would only need to authorize this agency on the "to whom" section of the consent form, rather than identify a specific individual at the agency to receive such information.

SAMHSA proposes to remove § 2.31(a)(4)(ii) and (iii)(A), and redesignate current § 2.31(a)(4)(iii)(B) as § 2.31(a)(4)(ii). SAMHSA also proposes to amend the newly redesignated § 2.31(a)(4)(ii), so that it applies only to entities that facilitate the exchange of health information (*e.g.*, health information exchanges (HIEs)) or research institutions. The proposed amendment would provide that, if the recipient entity is an entity that facilitates the exchange of health information or is a research institution, the consent must include the name of the entity and one of the following: (1) the name(s) of an individual or entity participant(s); or (2) a general designation of an individual or entity participant(s) or class of participants, limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed. As stated in the January 2017 final rule (82 FR 6084), for entities that facilitate the exchange of health information or are research institutions, SAMHSA wants to ensure that patient identifying information is only disclosed to those individuals and entities on the health care team with a need to know this sensitive information. Therefore, in instances where information is disclosed to entities that facilitate the exchange of health information or research institutions, SAMHSA will continue to limit the ability to use a general

designation (e.g., "all my treating providers") in the "to whom" section of the consent requirements to those individuals or entities with a treating provider relationship.

D. Prohibition on Re-disclosure (§ 2.32)

As discussed in Section III.B. above, in the 2017 final rule, SAMHSA clarified that the disclosure restrictions on SUD patient records would extend to individuals or entities who receive such records either from a part 2 program or from another lawful holder. We further emphasized this clarification in the notice requirements in § 2.32. Under § 2.32, each disclosure made with a patient's consent must contain a written statement notifying the recipient of the applicability of 42 CFR part 2 to any re-disclosure of the protected record. In the 2017 final rule, SAMHSA noted that the prohibition on re-disclosure provision only applies to information from the record that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder by a part 2-covered provider. The prohibition still allows other health-related information shared by the part 2 program to be re-disclosed, if permissible under the applicable law (82 FR 6089).

SAMHSA has heard from the provider community that this section of the regulation has prompted downstream, non-part 2 providers to manually redact portions of their disclosure data files that identify a patient as having or having had a substance use disorder. This activity is operationally burdensome and not the intent of the 2017 final rule. As noted in Section III.B. above, SAMHSA proposes to modify the regulations such 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 (and,

thus, subjected to part 2 protections), provided that any specific SUD records received from a part 2 program or other lawful holder are segregated or segmented. Therefore, a downstream entity would not need to redact SUD information in its records, provided that the original record received from the part 2 program or other lawful holder is segregated or segmented.

To ensure that downstream entities are aware that they do not need to redact information in their files if they have means of identifying the part 2-covered data (e.g., by segregating or segmenting the files received from the part 2 program), as proposed above, SAMHSA proposes to modify and streamline the notice language in § 2.32(a)(1), to remove the superfluous language that has contributed to confusion regarding the restrictions on re-disclosures. Specifically, we propose to remove "information in" and "that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person," from the current notice language established in the regulation. Additionally, SAMHSA has added language to specifically state that only the record is subject to the prohibition on re-disclosure in § 2.32, unless further disclosure either is expressly permitted by written consent of the individual whose information is being disclosed in the record or is otherwise permitted by 42 CFR part 2.

E. Disclosures Permitted with Written Consent (§ 2.33)

In the 2018 final rule (83 FR 241), SAMHSA clarified at § 2.33(b), the scope and requirements for permitted disclosures by a lawful holder to contractors, subcontractors, and legal representatives, for the purpose of payment and certain health care operations.

In the 2017 proposed rule, SAMHSA proposed to include a list of 17 specific types of permitted payment and health care operations (82 FR 5487).

Based on the numerous comments received requesting additions or clarifications to the list, as well as concerns that the changes occurring in the health care payment and delivery system could rapidly render any list of activities included in the regulatory text outdated, SAMHSA decided not to include the list of 17 activities in the regulation text in the 2018 final rule, and, instead, decided to include a list of the types of permitted activities in the preamble of the 2018 final rule. SAMHSA stated in the 2018 final rule that we included this list of activities in the preamble in order to make clear that it is an illustrative rather than exhaustive list of the types of payment and health care operations activities that would be acceptable to SAMHSA (83 FR 241). By removing the list from the regulatory text, SAMHSA intended for other appropriate payment and health care operations activities to be permitted under § 2.33 as the health care system continues to evolve.

Since the 2018 final rule was published, SAMHSA has learned that including an illustrative list of permissible activities in the preamble rather than in the text of the regulation did not fully clarify the circumstances under which part 2 information could be further disclosed under § 2.33. Specifically, stakeholders may believe that a particular activity is not permissible unless it is explicitly identified within the regulatory text. Therefore, to clear up any remaining confusion, SAMHSA proposes to amend § 2.33(b) to expressly include the illustrative list of permissible activities that was contained in the

preamble of the 2018 final rule (83 FR 243). It is important to note, as was noted in the preamble to the 2018 final rule, that this list is illustrative rather than exhaustive.

Specifically, examples of permissible activities that SAMHSA considers to be payment and health care operations activities to be added under § 2.33(b) include:

- 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; and
- Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges.

To further clarify that the list is not exhaustive, SAMHSA also proposes to add "other payment/health care operations activities not expressly prohibited" in this provision to the end of the list. For example, SAMHSA previously added language to the regulatory text in § 2.33(b) to clarify that disclosures to contractors, subcontractors and legal representatives are not permitted for activities related to a patient's diagnosis, treatment, or referral for treatment. SAMHSA again clarifies that § 2.33(b) is not intended to cover care coordination or case management, and disclosures to contractors, subcontractors, and legal representatives to carry out such purposes are not permitted under this section. We note that this policy differs from the Health Insurance Portability and Accountability Act Privacy Rule, under which 'health care operations' encompasses such activities as case management and care coordination. SAMHSA has previously emphasized the importance of maintaining patient choice in disclosing information to health care providers with whom they will have direct contact (83 FR 243). Although § 2.33(b) does not cover disclosures for the purpose of care coordination or case management, such disclosures may nevertheless be made under other provisions of §§ 2.31 and 2.33. Additionally, several of the proposals to revise other sections of part 2 in this rule-making will help to facilitate coordination of care, as under § 2.12 (Applicability).

F. Disclosures to Prevent Multiple Enrollments (§ 2.34)

In the 2017 final rule, SAMHSA modernized § 2.34 by updating terminology and revising corresponding definitions. Section 2.34 permits consensual disclosure of patient records to a withdrawal management or maintenance treatment program within 200 miles of a part 2 program. After receiving comments, we retained the specificity of "200 miles"

to prevent multiple enrollments that could result in patients receiving multiple streams of SUD treatment medications, which in turn may increase the likelihood of an adverse event or of diversion (82 FR 6094).

Central registries, defined in § 2.11, do not exist in all states, and the defining parameters for the operation of the registries vary somewhat across states and across part 2 programs. However, in the context of the opioid epidemic, recent experience has demonstrated that it is important for all providers who work with SUD patients, including non-opioid treatment program (non-OTP) providers, to have access to the information in the central registries, for the purpose of helping prevent duplicative patient enrollment for opioid use disorder treatment. Access to central registry information is also needed by non-OTP providers to fully inform their decisions when considering appropriate prescription drugs, including opioids, for their patients.

Methadone is a long-acting opioid used to treat opioid use disorders and for pain that, when used at levels higher than recommended for an individual patient, can lead to low blood pressure, decreased pulse, decreased respiration, seizures, coma, or even death. When used as a part of a supervised medication assisted treatment (MAT) program, methadone is a safe and effective treatment for SUD, including OUD. Methadone is a long acting opioid, subject to accumulation when its metabolism is inhibited. Its effects may be potentiated by certain other drugs with which it may have pharmacodynamic interactions, so the medication is specifically tailored to each individual patient and must be used exactly as prescribed. Exceeding the specific dosing can lead to dangerous side effects and potential overdose. Other medications, including other SUD treatments, such

as buprenorphine, as well as other medication including other opioids, benzodiazepines, HIV medications, certain antipsychotics and anti-depressants, also have the potential to interact dangerously with methadone.

Buprenorphine products are also long-acting opioid formulations approved by the Food and Drug Administration (FDA) for treatment of opioid use disorder, subject to limitations, which can be dispensed at OTPs, and in outpatient settings. While buprenorphine is demonstrated to exhibit a ceiling effect on respiratory depression in persons with opioid tolerance, it has significant opioid effects in those without tolerance which can contribute to adverse events including opioid overdose. Both of these long acting opioids (methadone and buprenorphine) have potential drug interactions with other medications that could lead to adverse events, including drug toxicity and opioid overdose.

These realities underscore the reason it is important for a prescriber to check central registries, when possible, to assure that it is appropriate to prescribe the contemplated opioid therapies for a particular individual. The ability to query a central registry regarding any duplicative enrollment in similar treatment can also be crucial to effective care, and to ensuring patient safety. Similarly, to avoid opioid-related adverse events, it is imperative that prescribing clinicians be aware of any opioid therapy that may be in current use by a patient prior to making further medication prescribing decisions.

Under the current language of § 2.34(a), a part 2 program may seek a written patient consent in order to disclose treatment records to a central registry. In turn, the

recipient central registry may only disclose–patient contact information for the purpose of preventing multiple enrollments under § 2.34(b). Currently, under § 2.34(c), the central registry may only disclose when asked by a "member program" whether an identified patient is enrolled in another member program.

SAMHSA proposes to expand the scope of § 2.34 to make non-OTP providers with 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 proposes to amend § 2.34(b) to include the use of central registry information to coordinate care with a non-part 2 program. In addition, we propose to add a new subsection (d) to specifically permit non-member treating providers to access the central registries. Previous subsection (d) will be re-designated as subsection (e).

SAMHSA believes that disclosures by central registries to non-OTP treating providers will help to ensure patient safety, and to prevent duplicative treatment plans and medications or medication doses that could place a patient receiving SUD treatment at risk.

For the reasons above, SAMHSA proposes to amend § 2.34(b) and (d) to allow non-OTP providers that have a treating relationship to the patient to access the central registries to inquire about that patient.

G. Disclosure to Prescription Drug Monitoring Programs (§ 2.36)

A prescription drug monitoring program (PDMP) is a statewide electronic database that collects, analyzes, and makes available prescription data on controlled substances prescribed by practitioners and non-hospital pharmacies.[3] Forty-nine states, St. Louis County, Missouri[4] and the District of Columbia have legislatively mandated the creation of PDMPs. Most states had developed their own PDMP prior to the current opioid crisis; however, few prescribers accessed them.[5] As opioid use disorder rates, overdoses and deaths increased significantly since 1999, the majority of states began requiring health professionals to check the state's PDMP[6] before prescribing controlled substances to patients. 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.[7] Studies have shown that states that have implemented such a requirement have seen declines in overall opioid prescribing, drug-related hospitalizations, and overdose deaths.[8]

[3] SAMHSA's Center for the Application of Prevention Technologies; Using Prescription Drug Monitoring Program Data to Support Prevention Planning. Available at: https://www.samhsa.gov/capt/sites/default/files/resources/pdmp-overview.pdf

[4] Former Missouri Gov. Greitens ordered the creation of a statewide PDMP in July 2017, but state lawmakers have not yet authorized funding for the program. St. Louis County started its own PDMP in April 2017, which covers nearly 80 percent (28 counties and 6 cities) of Missouri physicians and pharmacists.

[5] Brandeis University Prescription Drug Monitoring Program Training and Technical Assistance Center. Available at: http://www.pdmpassist.org/pdf/Resources/Briefing_on_mandates_3rd_revision_A.pdf.

[6] Pew Charitable Trusts and National Alliance for State Model Drug Laws. Available at: https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2017/12/29/in-opioid-epidemic-states-intensify-prescription-drug-monitoring.

[7] Pew Charitable Trusts. When are Prescribers Required to Use Prescription Drug Monitoring Programs? January 24, 2018. Available at: https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2018/when-are-prescribers-required-to-use-prescription-drug-monitoring-programs

[8] Brandeis University Prescription Drug Monitoring Program Training and Technical Assistance Center. Available at: http://www.pdmpassist.org/pdf/Resources/Briefing_on_mandates_3rd_revision_A.pdf..

Most PDMPs track prescription drug information on Schedule II-V controlled medications. Pharmacies must submit the prescription data required by their state's PDMP, depending on the state's statutory requirements. More robust PDMP programs have been associated with greater reductions in prescription opioid overdoses.[9] As noted above, this data allows providers to ensure that a patient is not receiving multiple prescriptions and to enhance patient care and patient safety.

Presently, OTPs are not required to report methadone or buprenorphine dispensing to their states' PDMP. In our 2011 guidance letter, SAMHSA encouraged OTP staff to access PDMPs, but stated that OTPs could not disclose patient identifying information to a PDMP unless an exception applies, consistent with the federal confidentiality requirements.[10] SAMHSA no longer believes this policy is advisable in light of the current public health crisis arising from opioid use, misuse, and abuse. In the past 10 years, there has been a substantial increase in prescription drug misuse, admissions to substance use facilities, emergency department visits and opioid-related deaths.[11] The omission of OTP data from a PDMP can lead to potentially dangerous adverse events for patients who may receive duplicate or potentially contraindicated prescriptions as part of medical care outside of an OTP, thereby placing them at risk for adverse events, including possible overdose or even fatal drug interactions.

[9] Pew Charitable Trusts. When are Prescribers Required to Use Prescription Drug Monitoring Programs? January 24, 2018. Available at: Available at: https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2018/when-are-prescribers-requiredd-to-use-prescription-drug-monitoring-programs

[10] Clark HW. Dear Colleague letter. September 27, 2011. Available at: https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/dear_colleague_letters/2011-colleague-letter-state-prescription-drug-monitoring-programs.pdf

[11] SAMHSA. In Brief: Prescription Drug Monitoring Programs: A Guide For Healthcare Providers. Volume 10, Issue 1 (Winter 2017). Available at: https://store.samhsa.gov/system/files/sma16-4997.pdf

SAMHSA believes that permitting part 2 programs, including OTPs, and lawful holders to enroll in PDMPs and submit the dispensing data for controlled substances required by states currently for other prescribed, controlled substances would allow for greater patient safety, better patient treatment, and better care coordination among the patient's providers. Therefore, SAMHSA proposes to add a new section § 2.36, permitting OTPs and other lawful holders to report the required data to their respective state PDMPs when dispensing medications. The proposed rule would require part 2 providers to obtain written consent from the patient whose identifying information will be disclosed prior to making such reports. This update is consistent with the proposal under § 2.34(c) to allow non-OTPs to query central registries to prevent duplicate enrollment.

SAMHSA acknowledges that this proposal may raise concerns about law enforcement access to PDMPs, particularly in those states in which PDMPs are operated by a law enforcement agency. However, individuals are not limited to OTPs when seeking OUD treatment. Prescriptions written for OUD opioid pharmacotherapy by non-OTP providers are already recorded in the state PDMP. By implication, PDMPs operated by law enforcement agencies are already receiving some patient data related to SUD treatment. Although the current proposal might expand that practice, it would not create it. And because the disclosure of SUD patient records by OTPs would be made contingent on written patient consent, any negative impact on patient confidentiality seems likely to be small. By contrast, the omission from PDMPs of dispensing and prescribing data from OTPs presents serious safety risks for SUD patients. While the reporting of patient data to a PDMP by an OTP would make it possible for law

enforcement, prescribers, and pharmacies with access to a PDMP to determine that a specific patient had received services at a specific OTP, law enforcement would still require a court order meeting the requirements of 42 U.S.C. 290dd-2(c) to access the covered records of that patient or any other patient served at the OTP. SAMHSA believes that allowing for OTP reporting to PDMPs further enhances PDMPs as a tool to help prevent prescription drug misuse and opioid overdose, while providing more complete and accurate data. In turn, more robust PDMP data is imperative for prescribers and providers to make better and more accurate patient care decisions while increasing patient safety and assuring appropriate care.

H. Medical Emergencies (§ 2.51)

Under § 2.51, disclosures of substance use disorder treatment records without patient consent are permitted in a bona fide medical emergency. Although not a defined term under part 2, a "bona fide medical emergency" most often refers to the situation in which an individual requires urgent clinical care to treat an immediately life-threatening condition (e.g., heart attack, stroke, overdose, etc.), and in which it is infeasible to seek the individual's consent to release of relevant, sensitive SUD records prior to administering potentially life-saving care. SAMHSA proposes to amend this section to address the impact of major[12] and natural disasters, declared by state or federal authorities, on access to substance use treatment and services, in addition to the more

[12] The Federal Emergency Management Agency (FEMA) notes that the President can declare a major disaster for any natural event, regardless of cause, that is determined to have caused damage of such severity that it is beyond the combined capabilities of state and local governments to respond. https://www.fema.gov/disaster-declaration-process

common situation of an individual experiencing a "bona fide medical emergency."

Disasters (e.g., hurricanes, wildfires) can present unique challenges for patients with substance use disorders, and for their treating providers. These events may disrupt the usual access to services and medications across a geographic region. As a result, patients may be required to seek treatment at facilities or with providers who do not have full access to their records.

When access to, or operation of, substance use disorder treatment facilities and services are disrupted on a regional basis in the wake of a disaster like a hurricane or wildfire, many patients become unable to access care through their usual providers, while many providers may be unable to follow usual consent-based procedures in order to obtain and/or release records for large numbers of patients. Thus, the disclosure requirements of 42 CFR part 2 may be too burdensome in these instances. For example, in the case of a hurricane, normal policies and procedures for obtaining consent according to §§ 2.31 and 2.32 may not be operational. At the same time, the inability of SUD patients to access needed care through their usual providers (or other providers) that have access to part 2-protected records concerning their condition, may constitute or lead to medical emergencies. As a result of these factors, SAMHSA believes that it is necessary – and consistent with its statutory authority – 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. In this NPRM, such an exception is proposed.

SAMHSA underscores that consent should still be obtained if at all feasible, but

appropriate care should be the priority in these often-devastating scenarios and an exception should be allowed. Thus, SAMHSA proposes to revise § 2.51(a) to facilitate expedient access to care for patients with SUDs during natural and major disasters. Specifically, SAMHSA proposes 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 effective ongoing substance use disorder services to patients in such disasters. Specifically, SAMHSA proposes that this medical emergency exception would apply only when a state or federal authority declares 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 resumes operations.

I. Research (§ 2.52)

SAMHSA recognizes the need for researchers to use SUD-related data to advance scientific research, particularly in light of the national opioid epidemic. SAMHSA supports the conduct of scientific research on SUD care, and has worked to allow researchers appropriate access to healthcare data relating to SUD, while maintaining appropriate confidentiality protections for patients.

Under 42 CFR § 2.52, part 2 programs are permitted to disclose patient identifying information for research, without patient consent, under limited circumstances. In the 2017 Final Rule, SAMHSA made several changes to the research exception at § 2.52, including permitting the disclosure of data by lawful holders (as well

as by part 2 programs) to qualified personnel for the purpose of conducting scientific research.

Currently § 2.52 allows the disclosure of patient identifying information for research purposes without patient consent, if the recipient of the patient identifying information is a HIPAA-covered entity or business associate, and has obtained and documented authorization from the patient, or a waiver or alteration of authorization, consistent with the HIPAA Privacy Rule at 45 CFR 164.508 or 164.512(i) or the recipient is subject to the HHS regulations regarding the protection of human subjects under the Common Rule. (45 CFR part 46).

Since the 2017 Final Rule, SAMHSA has become aware that limiting research disclosures under § 2.52, to only HIPAA-covered entities or institutions subject to the Common Rule,[13] may make it more difficult for some legitimate stakeholders to obtain data from SUD treatment records, for the purpose of conducting scientific research. For example, under the current provisions of § 2.52, the disclosure by a lawful holder of SUD records for the purpose of research to a State agency without a part 2 patient consent may be barred, given that most State agencies are neither HIPAA-covered entities nor directly subject to the Common Rule. It is not SAMHSA's intention or policy to make it more burdensome for these sorts of stakeholders to carry out scientific research. SAMHSA would like to more closely align the requirements of 42 CFR § 2.52 (disclosures for the purpose of research), with the currently analogous provisions on research under the

[13] The Common Rule governs research conducted or supported (i.e., funded) by the 16 departments and agencies that issued the Common Rule.

HIPAA Privacy Rule (45 CFR § 164.512(i)) and the Common Rule, in order to minimize any conflict or duplication in the requirements for consent to disclosure of records for the purpose of research. Therefore, SAMHSA is proposing to modify the text of § 2.52(a), in order 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 will align the requirements of part 2 with the Privacy Rule around the conduct of research on human subjects. SAMHSA believes this change to § 2.52(a) is needed, in order to allow an appropriate range of stakeholders to conduct scientific and public health research on SUD care and SUD populations.

In addition, SAMHSA is proposing two additional changes to the text of § 2.52(a). First, SAMHSA is proposing to add new § 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 requires all research activities carried out by its workforce to meet the requirements of either the Privacy Rule and/or Common Rule, as applicable. Second, SAMHSA is also proposing to add new § 2.52(a)(1)(iv), to permit research disclosures to recipients who are covered by FDA regulations for the protection of human subjects in clinical investigations (at 21 CFR Part 50), subject to appropriate documentation of compliance with FDA regulatory requirements, and pursuant to authority under the Food, Drugs and Cosmetics Act. In both instances, these proposals would help to align the part 2 requirements for research

disclosures of SUD data, with analogous requirements for the conduct of research on human subjects that may apply under other federal regulations in specific circumstances.

J. Audit and Evaluation (§2.53)

Current regulations at §§ 2.53(a), (b), and (c) describe the circumstances under which specified individuals and entities may access patient identifying information in the course of an audit or evaluation. Section 2.53(a) governs the disclosure of patient identifying information for audits and evaluations that do not involve the downloading, forwarding, copying, or removing of records from the premises of a part 2 program or other lawful holder. In these instances, information may be disclosed to individuals and entities who agree in writing to comply with the limitations on disclosure and use in § 2.53(d) and who perform the audit or evaluation on behalf of one of the following: a federal, state, or local governmental agency that provides financial assistance to or is authorized to regulate a part 2 program or other lawful holder; an individual or entity which provides financial assistance to a part 2 program or other lawful holder; a third-party payer covering patients in a part 2 program; or a quality improvement organization (QIO) performing a utilization or quality control review. The regulations permit disclosure to contractors, subcontractors, or legal representatives performing audits and evaluations on behalf of certain individuals, entities, third-party payers, and QIOs described directly above. At § 2.53(a)(2), the regulations also allow part 2 programs or other lawful holders to determine that other individuals and entities are qualified to conduct an audit or evaluation of the part 2 program or other lawful holder. In these instances, patient information may be disclosed during an on-premises review of records,

as long as the individuals and entities agree in writing to comply with the limitations on disclosure and use in § 2.53(d).

Section 2.53(b) of the regulation governs the copying, removing, downloading, or forwarding of patient records in connection with an audit or evaluation performed on behalf of government agencies, individuals, and entities described in 42 CFR § 2.53(b)(2), which are identical to the agencies, individuals, and entities described in § 2.53(a)(1) above. In these audits, records containing patient identifying information may be copied or removed from the premises of a part 2 program or other lawful holder, or downloaded or forwarded to another electronic system or device from the part 2 program's or other lawful holder's electronic records, by an individual or entity who agrees to the records maintenance standards and disclosure limitations outlined in § 2.53(b)(1)(i)-(iii).

Additionally, patient identifying information may be disclosed to individuals and entities who conduct Medicare, Medicaid, or CHIP audits or evaluations as set forth in § 2.53(c).

SAMHSA understands there is confusion about § 2.53 as it applies to several specific situations, and therefore proposes to make the following changes to the regulations to improve clarity about what is permissible under these sections. SAMHSA also proposes to update part 2 regulatory language related to quality improvement organizations (QIO) to align with current QIO regulations.

First, some stakeholders have voiced frustration that part 2 programs have been unwilling or unable to disclose patient records that may be needed by federal, state, and

local agencies, to better serve and protect patients with SUD. For example, a state Medicaid Agency or state or local health department may need to know about specific types of challenges faced by patients receiving opioid therapy treatment, such as co-occurring medical or psychiatric conditions, or social and economic factors that impede treatment or recovery. An agency may need this kind of information to recommend or mandate improved medical care approaches; to target limited resources more effectively to care for patients; or to adjust specific Medicaid or other program policies or processes related to payment or coverage to facilitate adequate coverage and payment. Government agencies may also wish to know how many patients test positive for a new and harmful illicit drug, and how part 2 programs are actually treating those patients, as an input to agency decisions aimed at improving quality of care. For example, agencies may wish to modify requirements for part 2 programs, educate or provide additional oversight of part 2 providers, and/or update corresponding payment or coverage policies. Third-party payers covering patients in a part 2 program may have similar objectives for obtaining part 2 information.

Current regulations allow part 2 programs to share information for the purposes described above in two ways, using either de-identified or identifiable information. Only SUD records containing patient identifying information are subject to part 2 protections, and therefore a part 2 program or other lawful holder may share non-identifiable information with government agencies (federal, state and local) for many types of activities.

SAMHSA encourages the use of de-identified or non-identifiable information

whenever possible. However, it may be time consuming, labor intensive, or technologically difficult for part 2 programs to create, and for government agencies to obtain quickly, data that does not contain part 2 identifying information. It may be too cumbersome or cost prohibitive for part 2 programs to provide the kind of data necessary in a de-identified format. It also may be challenging for part 2 programs to provide information quickly in more urgent situations, without potentially diverting resources away from patient care.

Patient identifying may also be used to help agencies and third-party payers improve care in certain circumstances. Under current regulations at § 2.53(a) and (b), federal, state, and local government agencies that have the authority to regulate or that provide financial assistance to part 2 programs, and third-party payers with covered patients in part 2 programs, may receive patient identifying information in the course of conducting audits or evaluations. Additionally, patient identifying information may be disclosed to individuals and entities to conduct Medicare, Medicaid, or CHIP audits or evaluations under § 2.53(c). Thus, a Medicaid agency may evaluate the part 2 providers that participate in its Medicaid program; a state health department may audit the facilities it licenses pursuant to its regulatory authority; and a health plan may review part 2 programs that serve its enrollees.

The current regulations do not define audit and evaluation, nor do they direct the manner in which evaluations are carried out, as noted by § 2.2(b)(2). Nevertheless, SAMHSA believes that the concept of audit or evaluation is not restricted to reviews that examine individual part 2 program performance. They may also include periodic reviews

of part 2 programs to determine if there are any needed actions at an agency level to improve care and outcomes across the individual part 2 programs the agency regulates or supports financially. Likewise, audits or evaluations may include reviews to determine if there are needed actions at a health plan level to improve care and outcomes for covered patients in part 2 program. In other words, audits or evaluations may be conducted with a goal to identify additional steps agencies or third-party payers should be taking to support the part 2 programs and their patients. This includes reviews that allow agencies or third-party payer entities to identify larger trends across part 2 programs, in order to respond to emerging areas of need in ways that improve part 2 program performance and patient outcomes.

SAMHSA proposes to clarify that under § 2.53, government agencies and third-party payer entities would be permitted to obtain part 2 records without written patient consent to periodically conduct audits or evaluations for purposes such as identifying agency or health plan actions or policy changes aimed at improving care and outcomes for part 2 patients (e.g., provider education, recommending or requiring improved health care approaches); targeting limited resources more effectively to better care for patients; or adjusting specific Medicaid or other insurance components to facilitate adequate coverage and payment. These agencies and third-party payers are required to abide by the restrictions on disclosure and other relevant confidentiality requirements outlined in § 2.53. Additionally, SAMHSA does not believe it is generally necessary to conduct these types of audits or evaluations on a routine or ongoing basis. Rather, we would generally expect that they would be performed periodically, unless they are required by applicable

law or other compelling circumstances exist, such as unique cases in which an oversight agency determines there is a need for ongoing review. Information disclosed for the purpose of a program audit or evaluation may not be used to directly provide or support care coordination. As stated previously (83 FR 243), SAMHSA believes it is important to maintain patient choice in disclosing information to health care providers with whom patients have direct contact. Agencies or health plans could, for example, use information from the aggregated results of part 2 program evaluations to determine that a new benefit or payment category is needed in order to facilitate better care coordination.

The preamble to the 2017 final rule noted that the authorizing statute for part 2 does not provide a general exception to the consent requirement for disclosure of SUD records, for the purpose of sharing records with public health officials (82 FR 6079). Furthermore, the preamble also noted that SAMHSA does not have the statutory authority to authorize routine disclosure of part 2 information for public health purposes (82 FR 6079). SAMHSA emphasizes that audits or evaluations using aggregated data for such purposes described above are distinct from a broader public health exception. Specifically, under current regulations, part 2 programs may share information with the agencies that have the authority to regulate or provide financial support to the part 2 program, in order to safeguard or improve the care and outcomes for current and future patients in those programs, or to ensure the integrity of the funding program and the appropriate use of financial support by the part 2 program. A broader public health exception would conceivably enable part 2 programs to share identifiable information with any public health agency, regardless of its relationship with the part 2 program, for many types of

purposes (e.g., preventative efforts aimed at a wider population).

To clarify allowable program evaluation activities using patient identifying information, SAMHSA proposes to redesignate current §§ 2.53(c) and (d) as §§ 2.53(e) and (f), respectively, and insert a new § 2.53(c) titled: *"Activities Included."* Proposed new paragraph § 2.53(c)(1) would specify that audits or evaluations may include periodic activities to identify actions that an agency or third-party payer entity can make, such as changing its policies or procedures to improve patient care and outcomes across part 2 programs; targeting limited resources more effectively; or determining the need for adjustments to payment policies for the care of patients with SUD. This change would clarify that disclosures of patient records by a part 2 program to an agency or third-party payer entity are permitted for these purposes without patient consent, pursuant to this section.

Second, SAMHSA has received feedback that stakeholders are unclear about whether § 2.53 allows federal, state, and local government agencies and third-party payers to have access to patient information for activities related to reviews of appropriateness of medical care, medical necessity, and utilization of services. As described above, the current regulations allow information to be disclosed to certain federal, state, and local governmental agencies and third-party payers for audit or evaluation purposes, as long as they agree to specific restrictions outlined in the regulations to limit disclosure or use of the records and preserve patient confidentiality. While neither the statute nor the regulations define audit or evaluation, these terms should and do include audits or evaluations to review whether patients are receiving appropriate

services in the appropriate setting. Assessing whether a part 2 program provides appropriate care is a necessary part of any comprehensive part 2 program audit or evaluation. Government agencies may be charged with conducting such reviews for licensing or certification purposes or to ensure compliance with federal or state laws, as may private not-for-profit entities granted authority under the applicable statutes or regulations to carry out such work in lieu of the agencies. Third-party payers also have a stake in the programmatic integrity, as well as the clinical quality, of the part 2 programs that serve the patients they cover. Therefore, SAMHSA proposes to insert a new § 2.53 (c)(2) that clarifies audit and evaluations under this section may include, but are not limited to, reviews of appropriateness of medical care, medical necessity, and utilization of services. Stakeholders are also referred to § 2.33, which allows disclosure of information for payment and/or health care operations activities with a patient's consent.

Third, stakeholders have expressed confusion about whether part 2 programs may disclose information for audit or evaluation purposes to the larger health care organizations in which they operate. For example, Medicare Condition of Participation regulations at 42 CFR § 482.21 require individual hospitals to conduct quality assessment and performance improvement (QAPI) programs that reflect the complexity of each hospital's organization and services, and which involve all hospital departments and services. QAPI programs are ongoing, hospital-wide, data-driven efforts that focus on addressing high-risk, high-volume or problem prone areas that affect health outcomes, patient safety, or quality of care.

The part 2 regulations provide ample leeway for part 2 programs to share information within their larger health care organizations for these and other types of evaluations. Under § 2.53(a)(2), part 2 programs may determine that individuals or entities within their health care organizations are qualified to conduct audits and evaluations and may share information pursuant to such reviews. Additionally, § 2.12(c)(3) states that, *"The restrictions on disclosure in the regulations in this part do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of patients with substance use disorders if the communications are:*

(i) Within a part 2 program; or

(ii) Between a part 2 program and an entity that has direct administrative control over the program." The phrase "direct administrative control" refers to the situation in which a substance use disorder unit is a component of a larger behavioral health program or of a general health program."

In order to eliminate any remaining misunderstanding, however, SAMHSA proposes to expand the regulatory language to explicitly clarify that this type of information sharing is permitted under the regulations. Specifically, we propose to add language to § 2.53(a)(2) to state that, "Auditors may include any non-part 2 entity that has direct administrative control over the part 2 program or lawful holder." Additionally. SAMHSA proposes to include similar language in new subsection (b)(2)(iii). We believe that the proposed changes will help to clarify that in these

situations, identifiable patient diagnosis or treatment information can be shared with personnel from an entity with direct administrative control over the part 2 program, where those persons, in connection with their audit or evaluation duties, need to know the information.

Fourth, while the regulations at §§ 2.53(a)(1)(ii) and (b)(2)(ii) specifically delineate that information may be disclosed to quality improvement organizations performing utilization or quality control reviews, these provisions do not explicitly include other types of entities that are responsible for quality assurance. For example, the regulations for audit and evaluation do not describe entities, such as health care organization accrediting or certification bodies, that may need to review patient records to evaluate whether a part 2 program meets quality and safety standards. To ensure that stakeholders understand that disclosure to these types of organizations is permitted, SAMHSA proposes to insert a new § 2.53(d) stating, "*Quality Assurance Entities Included*. Entities conducting audits or evaluations in accordance with §§ 2.53(a) and (b) may include accreditation or similar types of organizations focused on quality assurance."

Additionally, SAMHSA understands that some federal, state, and local government agencies face challenges in meeting statutory or regulatory mandates that require them to conduct audits or evaluations involving part 2 information. For example, the Centers for Medicare & Medicaid Services conducts risk adjustment data validation in connection with the risk adjustment program it is required to operate in accordance with section 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18063 and implementing regulations. Under risk adjustment data validation, health insurance

issuers are lawful holders of part 2 identifying information and may be required to provide it to CMS or its contractors. Therefore, SAMHSA is proposing to insert a new § 2.53(g) to permit patient identifying information to be disclosed to federal, state, and local government agencies, as well as their contractors, subcontractors, and legal representatives of such agencies, in the course of conducting audits or evaluations mandated by statute or regulation, if those audits or evaluations cannot be carried out using de-identified information.

In addition to these changes, SAMHSA proposes to update language related to quality improvement organizations. Specifically, at §§ 2.53(a)(1)(ii) and (b)(2)(ii), it proposes to amend the language to align it with the current QIO regulations.

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

Under the 1975 final rule, the placement of undercover agents or informants in a part 2 program was largely prohibited, other than as specifically authorized by a court order for the purpose of investigating a part 2 program, or its agents or employees, for allegations of serious criminal misconduct. At the time the 1975 final rule was promulgated, it was noted that, although the use of undercover agents and informants in treatment programs was ordinarily to be avoided, there occasionally arise circumstances where their use may be justified (42 FR 27809). More narrowly, it was noted that the authorizing statute, by itself, did not forbid the use of undercover agents or informants, and that the express statutory prohibition against direct disclosure of patient records is nevertheless subject to the power of the courts to authorize such disclosures under 42 USC 290dd-2(b)(2)(C). Building on these statutory considerations, it was concluded that

the power to regulate the placement of undercover agents and informants is limited, and that the importance of criminal investigation of part 2 programs offers a legitimate policy basis for allowing the placement of undercover agents or informants in such programs, given a showing of good cause in specific instances. As explained in the preamble to the 1975 final rule, experience has demonstrated that medical personnel, no matter how credentialed, can engage in the illicit sale of drugs on a large scale, and that the use of undercover agents and informants is normally the only effective means of securing evidence sufficient to support a successful prosecution in such instances. Based on over 40 years of experience since then, SAMHSA believes it is still the case that medical personnel sometimes engage in the illicit sale or transfer of drugs, and that a process for authorizing undercover agents is important to ensure the safety of patients in these part 2 programs.

Under the 1975 final rule, a 60-day time limitation with regard to the placement of undercover agents and informants in a part 2 program was imposed, with the opportunity for an applicant to seek an extension of the court order, for a total of up to 180 days (42 FR 27821). In the 1987 final rule, that period of placement for undercover agents and informants pursuant to a court order was extended to 6 months. This policy limitation was codified at § 2.67(d)(2).

Based on consultation with DOJ, the current policy is burdensome on, and overly restrictive of, some ongoing investigations of part 2 programs. Specifically, DOJ has stated that a typical undercover operation can often last longer than 6 months, and that 12 months is a more realistic timeframe for such operations. Therefore, SAMHSA proposes

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, DOJ has stated that the current regulation text is ambiguous regarding when the 6-month, or, as proposed, 12-month period, should start and stop, in determining whether a court-order period of placement has elapsed. SAMHSA considered multiple policy options regarding the tolling of the time period for an undercover placement. We considered having the time period begin on the date of the issuance of the court order. Alternatively, SAMHSA also considered having the time period begin on the date of placement of the undercover agent. In consultations with DOJ, SAMHSA has found that there is often a lag of time between the court order and the placement of the agent, for many reasons. Therefore, starting the time period when the court order is issued could significantly curtail the length of time an agent can be undercover at a part 2 program. Furthermore, starting the time period based on date of placement of the agent would provide greater clarity and predictability to law enforcement about exactly how long an agent or informant is allowed to be in the field, since the agent is aware of the date his or her placement began, but may not be aware of the date of the court order. Thus, SAMHSA proposes 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.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement can be approved by the Office of Management and Budget (OMB) for review and approval. Currently, the information collection is approved under OMB Control No. 0930–0092. The collection of information in this proposed rule has been submitted to OMB for review under section 3507(d) of the PRA, and any public comments on this collection of information should be directed to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for SAMHSA.

In order to fairly evaluate whether changes to an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that SAMHSA solicit comment on the following issues: (a) Whether the information collection is necessary and useful to carry out the proper functions of the agency; (b) The accuracy of the agency's estimate of the information collection burden; (c) The quality, utility, and clarity of the information to be collected; and (d) Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered in rule making. SAMHSA explicitly seeks, and will consider, public comment on our assumptions as they relate to the PRA requirements summarized in this section.

This proposed rule includes changes to information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, as defined under the

PRA (5 CFR part 1320). Some of the provisions involve changes from the information collections set out in the previous regulations. Below, SAMHSA briefly discusses each proposal and whether such proposal includes changes to information collection requirements.

In section III.A. of this proposed rule, SAMHSA proposes to modify the existing definition of "Records" in § 2.11 to conform with other proposed revisions in this proposed rule. See section III.A. for further information about this proposal. SAMHSA does not believe this proposal will result in any change in collection of information requirements since unrecorded information is, by its nature, not collected.

In section III.B. of this proposed rule, SAMHSA proposes to amend § 2.12 to clarify in that section that non-part 2 entities may record SUD treatment about a patient in its own records without triggering part 2 provided that such providers are able to differentiate their records from those received from a part 2 program and part 2 records received from lawful holders. See section III.B. for further information about this proposal. As stated in that section, SAMHSA proposes new regulatory text to clarify existing policies; thus, SAMHSA does not propose to change any collection of information requirements. Furthermore, we believe that the clarification represents standard practice in many, if not all, part 2 programs and among other lawful holders. That is, non-part 2 entities are already either segregating or segmenting any SUD records received from a part 2 program or deciding not to do so, based on their standard operations. This proposal would merely clarify that if the non-part 2 entity does, in fact, segregate or segment these records, the recording of information about a SUD and its

treatment by a non-part 2 entity does not by itself render a medical record subject to the restrictions of 42 CFR part 2. Thus, SAMHSA does not believe this proposal would result in any changes in collection of information requirements.

In section III.C. of this proposed rule, SAMHSA proposes to amend § 2.31, to allow patients to consent to disclosure of their information to entities, without naming the specific individual receiving this information on behalf of a given entity. See section III.C. for further information about this proposal. This proposal may result in providers needing to update their standard consent forms to allow for certain disclosures to such entities; that additional burden is discussed in the Regulatory Impact Analysis, below. SAMHSA believes this proposal may result in part 2 program disclosing more information to certain entities. We discuss this additional burden, in total, with the additional collection of information requirements that may result from the proposals in sections III.I., and III.J, below.

In section III.D. of this proposed rule, SAMHSA proposes to modify and streamline the language in § 2.32(a)(1), to remove the superfluous language that has contributed to confusion regarding the restrictions on re-disclosure. See section III.D. for further information about this proposal. Since part 2 providers are already required, upon disclosure, to provide a written statement notifying the recipient of the applicability of 42 CFR part 2 to any re-disclosure of the protected record, consistent with the prior revisions to part 2, including the 2017 final rule (82 FR 6106), SAMHSA does not believe this proposed modification of the language would result in any changes in collection of information requirements.

In section III.E. of this proposed rule, SAMHSA proposes to specify in regulatory text an illustrative list of 17 permitted activities under § 2.33. SAMHSA is also proposing to add to § 2.33 that other payment and/or health care operations activities not expressly prohibited under this provision are also allowed. See section III.E. for further information about this proposal. As noted in that section, SAMHSA has previously stated that these activities are permitted (83 FR 241); this proposed language would only further clarify this previously finalized policy. Therefore, SAMHSA does not believe this proposal would result in any changes in collection of information requirements.

In section III.F. of this proposed rule, SAMHSA proposes to expand the scope of § 2.34(d) to make non-OTP providers with a treating provider relationship eligible to query a central registry with their patient's consent to determine whether a patient is already receiving treatment through a member program to prevent duplicative enrollments and prescriptions for methadone or buprenorphine, as well as to prevent any adverse effects with other prescribed medications. See section III.F. for further information about this proposal. Based on SAMHSA's research, the policies and procedures governing central registries vary widely by each state; in fact, many states do not have central registries in place. Because of this lack of information, it is not possible to estimate either the number of additional queries which central registries may receive as a result of this proposal or the time or effort required to answer these queries. Therefore, it is difficult to estimate any additional collection of information requirements which may result from this proposal. Instead, SAMHSA requests that central registries and providers that would query central registries provide comments on any additional

information collection requirements this proposal would cause and any resulting burden.

In section III.G. of this proposed rule, SAMHSA proposes to add a new § 2.36 permitting part 2 programs to report any data for controlled substances dispensed or prescribed to patients to PDMPs, as required by the applicable state law. See section III.G. for further information about this proposal. SAMHSA anticipates that this proposal may result in additional burden for part 2 programs choosing to report to PDMPs in two ways. If a part 2 program chooses to report to a PDMP, the program will need to update its consent forms to request consent for disclosure to PDMPs. That burden is discussed in the Regulatory Impact Analysis, below. The second part of the proposal permits part 2 programs to report any data for controlled substances dispensed to patients to PDMPs, as required by the applicable state law. To estimate the additional collection of information requirements associated with this proposal, SAMHSA used the average number of opiate treatment admissions from SAMHSA's 2014–2016 Treatment Episode Data Set (TEDS) as the estimate of the number of clients treated on an annual basis by part 2 programs (531,965). Although not all programs would need to report this information under state law or may choose to do so, SAMHSA has used this number to be conservative and comprehensive of any future burden if states require reporting in the future. TEDS "comprises data that are routinely collected by States in monitoring their individual substance abuse treatment systems. In general, facilities reporting TEDS data are those that receive State alcohol and/or drug agency funds (including Federal Block Grant

funds) for the provision of substance abuse treatment."[14] Although TEDS does not represent all of the admissions to part 2 programs, as reporting varies by state, SAMHSA believes it represents the vast majority of admissions. Conservatively, we assumed that each of these clients would consent to the re-disclosure of their information to PDMPs and would be dispensed medication required to be reported to a PDMP. SAMHSA assumes that part 2 programs, based on other state and federal requirements, already are required to query PDMP databases; therefore, SAMHSA does not include registration and infrastructure costs in this estimate. For example, several states require medical directors of OTPs to query their respective state PDMPs at minimum intervals, including IN, MN, MI, ND, NC, RI, TN, VT, WA, and WV.[15] Based on discussions with providers, SAMHSA also estimates that, in addition to an initial update to the PDMP database for existing patients, the PDMP database would typically need to be accessed and updated quarterly for each patient, on average. Likewise, based on discussion with providers, SAMHSA believes accessing and reporting to the database would take approximately 2 minutes per patient, resulting in a total annual burden of 8 minutes (4 database accesses/updates x 2 minutes per access/update) or 0.133 hours annually per patient. For the labor costs associated with this activity, SAMHSA used the average wage rate of $23.04[16] per hour for substance abuse and behavioral disorder counselors

[14] https://wwwdasis.samhsa.gov/webt/information.htm.

[15] https://www.pdmpassist.org/pdf/Resources/Use%20of%20PDMP%20data%20by%20opioid%20treatment%20programs.pdf

[16] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Employment Statistics*, May 2018, Substance Abuse and Behavioral Disorder Counselors, Standard Occupations Classification code (21-1018) [*www.bls.gov/oes/current/oes_nat.htm*].

(multiplied by two to account for benefits and overhead costs) to estimate a total burden in year 1 for the initial update of the PDMP database of $817,098 (531,965 clients x 2 minutes (0.033 hrs) per access/update x $46.08/hr) and an annual burden in each year of $3,268,391 (531,965 clients x 0.133 hours x $46.08/hr). Therefore, we estimate that this proposal will result in an additional cost of $4,085,489 ($817,098 + $3,268,391), as reflected in Table 1, below.

In section III.H. of this proposed rule, SAMHSA proposes an addition to § 2.51 to allow disclosure of patient information during natural and major disasters. See section III.H. for further information about this proposal. Because this proposal by its very nature does not require additional consent requirements or other paperwork, SAMHSA does not believe this proposal would result in any changes in collection of information requirements. Providers, under their own policies and procedures or other laws, may need to keep track of the disclosures made, which, could require additional paperwork. Such requirements, however, are not discussed in this rule, nor does SAMHSA have any way of estimating them, as policies and procedures may vary across providers.

In section III.I., and section III.J. of this proposed rule, SAMHSA proposes to amend § 2.52 and § 2.53 to allow certain disclosures without patient consent. First, in section III.I. of this proposed rule, SAMHSA proposes to modify the text of § 2.52(a) in order 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. See section III.I. for further information

about this proposal. Second, SAMHSA proposes to clarify allowed disclosures for audit and evaluation purposes under § 2.53 for activities undertaken by a federal, state, or local governmental agency or third-party payer to improve the delivery of care, to target limited resources more effectively and/or to determine the need for adjustments to payment policies for the care of patients with SUD. SAMHSA also proposes language to clarify that (1) audits and evaluations may include reviews of appropriateness of medical care, medical necessity, and utilization of services; (2) part 2 programs may disclose information, without consent, to non-part 2 entities that have direct administrative control over such part 2 programs; and (3) entities conducting audits or evaluations in accordance with §§ 2.53(a) and (b) may include accreditation or similar types of organizations focused on quality assurance. Further, SAMHSA proposes to permit patient identifying information to be disclosed to government agencies in the course of conducting audits or evaluations mandated by statute or regulation, if those audits or evaluations cannot be carried out using de-identified information. Finally, SAMHSA is proposing to update language related to QIOs. See section III.J. for further information about these proposals. As stated in that section, SAMHSA believes that the regulations already permit audits and evaluations for reviews of appropriateness of medical care, medical necessity, and utilization of services. Likewise, SAMHSA also believes that the current regulations permit disclosure to a non-part 2 entity with direct administrative control over a part 2 program and to accreditation and similar organizations. Therefore, although SAMHSA proposes language to clarify any confusion that may exist, it believes that these activities are already permitted and that they would not, therefore, result in any

new collection of information requirements or any other burden. It also believes updating the QIO language would not create new collection of information requirements or increase burden. As noted above, SAMHSA also proposes to allow patient identifying information to be disclosed to government agencies and third-party payers periodically to identify needed actions at the agency or payer level, and to contractors hired by health insurance issuers and government agencies in the course of conducting audits or evaluations mandated by statute or regulation, if those audits and evaluations cannot be carried out using de-identified information. In section III.C of this proposed rule, SAMHSA also proposes to allow disclosure to entities with patient consent. SAMHSA believes that the proposals in sections III.C., I, and J, may result in additional collection of information requirements, as part 2 programs may be asked to disclose information to agencies and entities as a result of these proposals. Although SAMHSA is not able to anticipate the increase in these disclosures, to estimate the potential cost, we first estimated the number of potentially impacted part 2 programs based on the anticipated number of requests for a disclosure in a calendar year. SAMHSA used the average number of substance abuse treatment admissions from SAMHSA's 2014–2016 TEDS (1,658,732) as the number of patients treated annually by part 2 programs. SAMHSA then estimated that part 2 programs would need to disclose average of 15 percent of these records (248,810) as a result of these proposals. We then estimated that 10 percent or 24,881 (248,810 x 10%) of impacted part 2 programs would use paper records to comply with these requests for disclosure reports while the remaining 90% or 223,929 (248,810 x 90%) would use a health IT system. For part 2 programs using paper records, SAMHSA

expects that a staff member would need to gather and aggregate the information from paper records, and manually track disclosures; for those part 2 programs with a health IT system, we expect records and tracking information would be available within the system.

SAMHSA assumed medical record technicians would be the staff with the primary responsibility for compiling the information for a list of disclosures from both paper records and health IT systems. The average hourly rate for medical record and health information technicians is $21.16.[17] In order to account for benefits and overhead costs associated with staff time, we multiplied the hourly wage rate by two for a total average hourly wage rate of $42.32. Absent any existing information on the amount of time associated with producing a list of disclosures, SAMHSA assumed it would take a medical record technician 4 hours, on average, to produce the information from paper records at a cost of $169.28 (4 hours x $42.32/hr) and 0.25 hours, on average, to produce information from a health IT system at a cost of $10.58 (0.25 hours x $42.32/hr). Finally, SAMHSA assumes that agencies will request that these disclosures be made on secure, online databases, and would not require notification via email or first class mail, thus resulting in no additional cost to transmit this information. Based on these assumptions, SAMHSA estimates that this proposal would result in an additional cost of $6,581,025 {(24,881 requests x $169.28 per request) + (223,929 requests x $10.58 per request)}, as reflected in Table 1, below.

[17] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Employment Statistics*, May 2018, Medical Records and Health Information Technicians, Standard Occupations Classification code (29-2071) [*www.bls.gov/oes/current/oes_nat.htm*].

In section III.K. of this proposed rule, SAMHSA proposes to amend § 2.67 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 that section, SAMHSA also proposes to explicitly state when the 12-month period begins to run. See section III.K. for further information about this proposal. The requirements of the Paperwork Reduction Act do not apply "During the conduct of a Federal criminal investigation or prosecution, or during the disposition of a particular criminal matter" (5 CFR § 1320.4(a)(1)), or to information collections by the federal judiciary or state courts (5 CFR § 1320.3(a)), except in the rare case that those information collections and conducted or sponsored by an executive branch department (5 CFR § 1320.3(a)).

Below, SAMHSA summarizes the estimated cost of the change in collection of information requirements discussed above.

Table 1: Annualized Burden Estimates

	Annual Number of Respondents	**Responses per Respondent**	**Total Responses**	**Hours per Response**	**Total Hourly Burden**	**Hourly Wage Cost**	**Total Hourly Cost**
§2.36	531,965	5	2,659,825	0.033	88,661	$46.08	$4,085,489
§§ 2.31,	24,881	1	24,881	4	99,524	$42.32	$4,211,856

2.52, 2.53 (Paper Records)							
§§ 2.31, 2.52, 2.53 (Health IT Systems)	223,929	1	223,929	0.25	55,982	$42.32	$2,369,169
Total	780,775		2,908,633		244,167		$10,666,513

V. Response to Comments

Because of the large number of public comments SAMHSA anticipates receiving on this **Federal Register** document, it will not be able to acknowledge or respond to them individually. SAMHSA will consider all comments received by the date and time specified in the **DATES** section of this proposed rule. When SAMHSA proceeds with a subsequent document, it will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary to update the Confidentiality of Substance Use Disorder Patient Records regulations at 42 CFR part 2 to respond to the emergence of the opioid crisis, with its catastrophic impact on patients and corresponding clinical and safety challenges for providers. The goal of this proposed rule is to clarify existing requirements in 42 CFR part 2 and reduce barriers to information sharing to ensure appropriate care and patient safety.

As noted in the tables below, SAMHSA believes that the proposed policies in this proposed rule, if finalized, would result in some near-term non-recurring and annual recurring financial burdens. We have weighed these potential burdens against the potential benefits, and believe, on balance, the potential benefits outweigh any potential costs. Specifically, the proposals in this rule are meant to allow providers to better understand the needs of their patients by clarifying the requirements under part 2 and to break down barriers to information sharing among part 2 programs and other providers. SAMHSA believes this information sharing would benefit patients because both part 2 programs and other providers would be able to more fully understand the patient's health history and avoid dangerous and even lethal adverse drug events. In addition, these proposals are also intended to protect and empower patients by giving them more control over their consent and control of their records, for example, by allowing them to consent to disclosure to entities, should they so choose. Furthermore, in drafting these proposals, SAMHSA was cognizant of privacy concerns and specifically drafted these proposals to

protect the privacy of patients; for example, the proposal regarding OTP provider disclosure to PDMPs requires the consent of the patient. SAMHSA believes that increasing patient safety and the empowerment of patients would lead to better health outcomes, therefore balancing any burdens discussed below and any remaining privacy concerns. ÷

B. Overall Impact

SAMHSA has examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 (Reducing and Controlling Regulatory Costs). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory "action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities

(also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus, is not considered a major rule to which Executive Orders 12866 or 13771 apply.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses (including independent contractors), nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. The proposed rule would allow patients to consent to disclosure of their information to entities; permit part 2 programs to report data for controlled substances dispensed to patients to PDMPs with patient consent; and allow part 2 programs to comply with disclosure requests from federal, state, or local governmental agencies, third-party payers and researchers. These proposals will result in additional reporting burden as well as near-term non-recurring and annual recurring regulatory impacts to part 2 programs. As shown in Table 2 and as discussed in the Collection of Information Requirements (Section IV), we estimate the average cost impact per substance abuse treatment admission for staff training, updates to consent forms, and disclosures to agencies will be $4.09 in year 1 ($6,782,493 ÷

1,658,732 patients) and $3.97 in years 2 through 10 ($6,581,025 ÷ 1,658,732 patients). For opiate treatment patients, we also estimate the average cost impact for disclosure to PDMPs to be $7.68 per patient in year 1 ($4,085,489 ÷ 531,965 patients) and $6.14 in years 2 through 10 ($3,268,391 ÷ 531,965 patients). When this is added to the costs for staff training, updates to consent forms, and disclosures to agencies, the aggregate cost impact per opiate treatment admission is $11.77 in year 1 and $10.11 in years 2 through 10. While we are unable to determine how many part 2 programs qualify as small businesses based on the minimum threshold for small business size of $38.5 million (https://www.sba.gov/federal-contracting/contracting-guide/size-standards), we believe that on a per-patient basis, this proposed rule will not significantly affect part 2 treatment programs of any size. SAMHSA has not prepared an analysis for the RFA because it has determined, and the Secretary certifies, that this rule, if finalized as proposed, would not have a significant economic impact on a substantial number of small entities.

As further described in section IV., above, when estimating the total costs associated with changes to the 42 CFR part 2 regulations, SAMHSA estimated costs related to collection of information for the proposed changes to §§ 2.31, 2.52, 2.53, and (new) 2.36. In addition, we estimate that there may be additional burden related to updating consent forms as a result of the proposals in §§ 2.31 and (new) 2.36. In section III.C. of this proposed rule, SAMHSA proposes to amend § 2.31, to allow patients to consent to disclosure of their information to entities, without naming the specific individual receiving this information on behalf of a given entity. In section III.G. of this proposed rule, SAMHSA proposes to add a new § 2.36, permitting part 2 programs to

report to PDMPs; patients must consent to disclosure before this reporting can occur. See sections III.C. and III.G. for further information about these proposals. These proposals may result in providers needing to update their standard consent forms to allow for certain disclosures. As stated in the 2016 proposed rule (81 FR 7009 through 7010), based from a 2008 study from the Mayo Clinic Health Care Systems,[18] the reported cost to update authorization forms was $0.10 per patient. Adjusted for inflation,[19] costs associated with updating the patient consent forms in 2019 would be $0.12 per patient (2018 dollars). SAMHSA used the average number of substance abuse treatment admissions from SAMHSA's 2014–2016 TEDS (1,658,732) as an estimate of the number of clients treated on an annual basis by part 2 programs. Therefore, the total cost burden associated with updating the consent forms to reflect the updated 42 CFR part 2 regulations is estimated to be a one-time cost of $199,048 (1,658,732 * $0.12), as reflected in Table 2, below. Further, the proposal to amend § 2.31 is likely to result in a decrease in the number of consents to disclosures that patients must make, due to the ability to consent to entities without naming a specific individual. Because of a lack of data regarding the number of consents patients have made to multiple individuals within the same entity which would become duplicative as a result of the proposed amendment, we are unable to quantify the reduction in burden related to the expected reduction in the number of required consents.

[18] Williams, A.R., Herman, D.C., Moriarty, J.P., Beebe, T.J., Bruggeman, S.K., Klavetter, E.W. & Bartz, J.K. (2008). HIPAA costs and patient perceptions of privacy safeguards at Mayo Clinic. *Joint Commission Journal on Quality and Patient Safety, 34*(1), 27–35.
[19] https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-201905.pdf

In prior proposed rules (e.g., 81 FR 7009), SAMHSA estimated one hour of training per staff to achieve proficiency in the 42 CFR part 2 regulations. SAMHSA assumes that training associated with the new requirements discussed in this proposed rule can be accomplished within the existing one hour of training, therefore we are not proposing any additional costs for training counseling staff.

With regard to training materials, SAMHSA will assume responsibility for updating and distributing training materials in year 1 at no cost to part 2 programs. A 2017 study by the Association for Talent Development determined the average time to develop training materials for one hour of classroom instruction is 38 hours[20]. Because we assume that SAMHSA will be updating rather than developing training materials, we estimate the time for training development to be one-half that of developing new materials, or 19 hours and would be performed by an instructor with experience in healthcare at the average wage rate of $63.71 per hour for a health specialty teacher[21] and multiplied the average wage rate by 2 in order to account for benefits and overhead costs. Based on these assumptions, the updating of training materials is estimated to cost $2,421 (19 hours x $127.42/hour). SAMHSA estimates that the updates to consent forms (§§ 2.31 and 2.36) would be one-time costs the first year the final rule would be in effect and would not carry forward into future years. Staff training costs other than those associated with updating training materials are assumed to be ongoing annual costs to

[20] https://www.td.org/insights/how-long-does-it-take-to-develop-one-hour-of-training-updated-for-2017
[21] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Employment Statistics*, May 2018, Health Specialty Teachers, Postsecondary, Standard Occupations Classification code (25-1071) [*www.bls.gov/oes/current/oes_nat.htm*].

part 2 programs, also beginning in the first year that the final rule is in effect. Costs associated with disclosing information to PDMPs (§ 2.36) and agencies (§ 2.53) are assumed to be ongoing annual costs to part 2 programs.

In section III.K. of this proposed rule, SAMHSA proposes to amend § 2.67 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 that section, SAMHSA also proposes to explicitly state when the 12-month period begins to run. See section III.K. for further information about this proposal. Since the requirements for seeking this court order would be the same, and the proposal would merely be extending the time of the court order, SAMHSA does not believe this proposal will result in any additional regulatory burden.

Based on the above, SAMHSA estimates in the first year that the final rule would be in effect, the costs associated with the proposed updates to 42 CFR part 2 would be $10,867,982 as shown in Table 2. In years 2 through 10, SAMHSA estimates that costs would be $9,849,415. Over the 10-year period of 2019–2028, the total undiscounted cost of the proposed changes would be $99,512,721 in 2018 dollars. As shown in Table 3, when future costs are discounted at 3 percent or 7 percent per year, the total costs become approximately $85.0 million or $70.1 million, respectively. These costs are presented in the tables below.

TABLE 2: TOTAL COST OF 42 CFR PART 2 REVISIONS

Year	Disclosure to	Staff	Updates to	Disclosures	Total Costs

	PDMPs	Training Costs	Consent Forms	to Agencies	
2019	$4,085,489	$2,421	$199,048	$6,581,025	$10,867,982
2020	$3,268,391	0	0	$6,581,025	$9,849,415
2021	$3,268,391	0	0	$6,581,025	$9,849,415
2022	$3,268,391	0	0	$6,581,025	$9,849,415
2023	$3,268,391	0	0	$6,581,025	$9,849,415
2024	$3,268,391	0	0	$6,581,025	$9,849,415
2025	$3,268,391	0	0	$6,581,025	$9,849,415
2026	$3,268,391	0	0	$6,581,025	$9,849,415
2027	$3,268,391	0	0	$6,581,025	$9,849,415
2028	$3,268,391	0	0	$6,581,025	$9,849,415
TOTAL	$33,501,007	$2,421	$199,048	$65,810,245	$99,512,721

TABLE 3: TOTAL COST OF 42 CFR PART 2 REVISIONS – ANNUAL DISCOUNTING

Year	Total Costs	Total Cost with 3% Discounting	Total Cost with 7% Discounting
2019	$10,867,982	$10,551,439	$10,156,992
2020	$9,849,415	$9,284,019	$8,602,861
2021	$9,849,415	$9,013,610	$8,040,057

2022	$9,849,415	$8,751,078	$7,514,072
2023	$9,849,415	$8,496,192	$7,022,497
2024	$9,849,415	$8,248,730	$6,563,081
2025	$9,849,415	$8,008,476	$6,133,721
2026	$9,849,415	$7,775,219	$5,732,449
2027	$9,849,415	$7,548,757	$5,357,429
2028	$9,849,415	$7,328,890	$5,006,943
TOTAL	$99,512,721	$85,006,411	$70,130,104

C. Alternatives Considered

In drafting this proposed rule, SAMHSA considered potential policy alternatives and, when possible, proposed the least burdensome alternatives. For example, in section III.B. of this proposed rule, we considered specifically proposing the technological and operational requirements required for segmenting records but decided to allow providers more latitude to define their best practices, understanding that specific requirements could pose more burden, specifically to small and rural providers. In section III.C. of this proposed rule, SAMHSA also considered only allowing patients to allow disclosure to state, federal, and local government entities that provide benefits. Instead, however, it decided to propose to allow patients to more broadly specify disclosure to entities, so that patients can more widely control their information. On balance, SAMHSA believes that the proposals in this rule most appropriately balance the often-competing interests of burden, privacy, and patient safety.

D. Conclusion

SAMHSA is proposing to amend 42 CFR part 2. With respect to our proposal to revise the regulations, SAMHSA does not believe that the proposal would have a significant impact. As discussed above, we are not preparing an analysis for the RFA because SAMHSA has determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities. SAMHSA is not preparing an analysis for section 1102(b) of the RFA because it has determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals. In addition, SAMHSA does not believe this rule imposes substantial direct effects on (1) states, including subdivisions thereof, (2) the relationship between the federal government and the states, or (3) the distribution of power and responsibilities among the various levels of government. Therefore, the requirements of Executive Order 13132 on federalism would not be applicable.

SAMHSA invites public comments on this section and requests any additional data that would help it to determine more accurately the impact on individuals and entities of the proposed rule. In accordance with the provisions of Executive Order 12866, this proposed rule has been reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR part 2

Alcohol abuse, Alcoholism, Drug abuse, Grant programs-health, Health records, Privacy, Reporting and Recordkeeping requirements.

VII. Regulation Text

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend **42 CFR part 2** to read as follows:

PART 2—CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS

1. The authority citation for part 2 continues to read as follows:

Authority: Sec. 408 of Pub. L. 92–255, 86 Stat. 79, as amended by sec. 303(a), (b) of Pub L. 93–282, 83 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94–237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94–581, 90 Stat. 2852; sec. 509 of Pub. L. 96–88, 93 Stat. 695; sec. 973(d) of Pub. L. 97–35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98–24, 97 Stat. 182 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290ee–3) and sec. 333 of Pub. L. 91–616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93–282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94– 581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L. 98–24, 97 Stat. 181 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290dd–3), as amended by sec. 131 of Pub. L. 102–321, 106 Stat. 368, (42 U.S.C. 290dd–2).

2. Amend § 2.11 by revising the definition of "Records" to read as follows:

§ 2.11 Definitions.

* * * * *

Records means any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient (e.g., diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts), provided, however, 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 become a record subject to this Part in the possession of the non-part 2 provider merely because that information is reduced to writing by that non-part 2 provider. Records otherwise transmitted by a part 2 program to a non-part 2 provider retain their characteristic as records in the hands of the non-part 2 provider, but may be segregated by that provider. For the purpose of the regulations in this part, records include both paper and electronic records.

* * * * *

3. Amend § 2.12 by:

a. Revising paragraphs (a)(1) introductory text and (a)(1)(ii);

b. Adding paragraph (d)(2)(ii); and

c. Revising paragraphs (e)(3) and (4) introductory text.

The revisions and additions read as follows:

§ 2.12 Applicability.

(a) * * *

(1) *Restrictions on disclosure*. The restrictions on disclosure in the regulations in this part apply to any records which:

* * * * *

(ii) Contain drug abuse information obtained by a federally assisted drug abuse

program after March 20, 1972 (part 2 program), or contain alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (part 2 program); or if obtained before the pertinent date, is maintained by a part 2 program after that date as part of an ongoing treatment episode which extends past that date; for the purpose of treating a substance use disorder, making a diagnosis for that treatment, or making a referral for that treatment.

* * * * *

(d) * * *

(2) * * *

(ii) Notwithstanding paragraph (2)(i)(C) of this section, a non-part 2 treating provider may record information about a substance use disorder (SUD) and its treatment that identifies a patient. This is permitted and does not constitute a record that has been re-disclosed under part 2, provided that any SUD records received from a part 2 program or other lawful holder are segregated or segmented. The act of recording information about a SUD and its treatment does not by itself render a medical record which is created by a non-part 2 treating provider subject to the restrictions of this part 2.

* * * * *

(e) * * *

(3) *Information to which restrictions are applicable.* Whether a restriction applies to the use or disclosure of a record affects the type of records which may be disclosed. The restrictions on disclosure apply to any part 2-covered records which would identify a specified patient as having or having had a substance use disorder. The restriction on use

of part 2 records to bring criminal charges against a patient for a crime applies to any records obtained by the part 2 program for the purpose of diagnosis, treatment, or referral for treatment of patients with substance use disorders. (Restrictions on use and disclosure apply to recipients of part 2 records under paragraph (d) of this section.)

(4) *How type of diagnosis affects coverage.* These regulations cover any record reflecting a diagnosis identifying a patient as having or having had a substance use disorder which is initially prepared by a part 2 provider in connection with the treatment or referral for treatment of a patient with a substance use disorder. A diagnosis prepared by a part 2 provider for the purpose of treatment or referral for treatment, but which is not so used, is covered by the regulations in this part. The following are not covered by the regulations in this part:

* * * * *

4. Amend § 2.31 by revising paragraph (a)(4) to read as follows:

§ 2.31 Consent requirements.

(a) * * *

(4)(i) The name(s) of the individual(s) or the name(s) of the entity(-ies) to which a disclosure is to be made.

(ii) *Special instructions for entities that facilitate the exchange of health information and research institutions*. Notwithstanding paragraph (a)(4)(i) of this section, if the recipient entity facilitates the exchange of health information or is a research institution, a written consent must include the name(s) of the entity(-ies) and

(A) The name(s) of individual or entity participant(s); or

(B) A general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed. When using a general designation, a statement must be included on the consent form that the patient (or other individual authorized to sign in lieu of the patient), confirms their understanding that, upon their request and consistent with this part, they must be provided a list of entities to which their information has been disclosed pursuant to the general designation (*see* §2.13(d)).

* * * * *

5. Amend § 2.32 by revising paragraph (a)(1) to read as follows:

§ 2.32 Prohibition on re-disclosure.

(a) * * *

(1) This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of this record unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or, is otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see §2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§2.12(c)(5) and 2.65; or

* * * * *

6. Amend § 2.33 by revising paragraph (b) to read as follows:

§ 2.33 Disclosures permitted with written consent.

* * * * *

(b) If a patient consents to a disclosure of their records under §2.31 for payment and/or health care operations activities, a lawful holder who receives such records under the terms of the written consent may further disclose those records as may be necessary for its contractors, subcontractors, or legal representatives to carry out payment and/or health care operations on behalf of such lawful holder. Disclosures 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. In accordance with §2.13(a), disclosures under this section must be limited to that information which is necessary to carry out the stated purpose of the disclosure. Examples of permissible payment and/or health care operations activities under this section include:

(1) Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing, and/or related health care data processing;

(2) Clinical professional support services (e.g., quality assessment and improvement initiatives; utilization review and management services);

(3) Patient safety activities;

(4) Activities pertaining to:

(i) The training of student trainees and health care professionals;

(ii) The assessment of practitioner competencies;

(iii) The assessment of provider and/or health plan performance; and/or

(iv) Training of non-health care professionals;

(5) Accreditation, certification, licensing, or credentialing activities;

(6) 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;

(7) Third-party liability coverage;

(8) Activities related to addressing fraud, waste and/or abuse;

(9) Conducting or arranging for medical review, legal services, and/or auditing functions;

(10) 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;

(11) Business management and general administrative activities, including management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations;

(12) Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;

(13) Resolution of internal grievances;

(14) The sale, transfer, merger, consolidation, or dissolution of an organization;

(15) 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;

(16) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(17) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges; and/or

(18) Other payment/health care operations activities not expressly prohibited in this provision.

* * * * *

7. Amend § 2.34 by:

a. Revising paragraph (b);

b. Redesignating paragraph (d) as paragraph (e); and

c. Adding a new paragraph (d).

The revisions and addition read as follows:

§ 2.34 Disclosures to prevent multiple enrollments.

* * * * *

(b) *Use of information limited to prevention of multiple enrollments.* A central registry and any withdrawal management or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not re-disclose or use patient identifying information for any purpose other than the prevention of multiple

enrollments or to ensure appropriate coordinated care with a treating provider that is not a part 2 program unless authorized by a court order under subpart E of this part.

* * * * *

(d) *Permitted disclosure by a central registry to a non-member treating provider, to prevent a multiple enrollment*. When, for the purpose of preventing multiple program enrollments or duplicative prescriptions, or to inform prescriber decision making regarding prescribing of opioid medication(s) or other prescribed substances, a provider with a treating provider relationship that is not a member program asks a central registry if an identified patient is enrolled in a member program, the registry may disclose:

(1) The name, address, and telephone number of the member program(s) in which the patient is enrolled;

(2) Type and dosage of any medication for substance use disorder being administered or prescribed to the patient by the member program(s); and

(3) Relevant dates of any such administration or prescription. The central registry and non-member program treating prescriber may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollments or improper prescribing.

* * * * *

8. Add § 2.36 to Subpart C to read as follows:

§ 2.36 Disclosures to prescription drug monitoring programs.

Permitted disclosure by a part 2 program or other lawful holder to a prescription drug monitoring program. A part 2 program or other lawful holder is permitted to report

any SUD medication prescribed or dispensed by the part 2 program to the applicable state prescription drug monitoring program if required by applicable state law. A part 2 program or other lawful holder must obtain patient consent to a disclosure of records under § 2.31 prior to reporting of such information.

9. Amend § 2.51 by revising paragraph (a) to read as follows:

§ 2.51 Medical emergencies.

(a) *General rule.* Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed o medical personnel to the extent necessary to:

(1) Meet a bona fide medical emergency in which the patient's prior informed consent cannot be obtained; or

(2) Meet a bona fide medical emergency in which a part 2 program is closed and unable to provide services or obtain the prior written consent of the patient, during a temporary state of emergency declared by a state and/or federal authority as the result of a natural or major disaster, until such time that the part 2 program resumes operations.

* * * * *

10. Amend § 2.52 by revising paragraph (a) to read as follows:

§ 2.52 Research.

(a) Notwithstanding other provisions of this part, including paragraph (b)(2) of this section, patient identifying information may be disclosed_for the purposes of the recipient conducting scientific research if:

(1) The individual designated as director or managing director, or individual otherwise vested with authority to act as chief executive officer or their designee, of a part 2 program or other lawful holder of part 2 data, makes a determination that the recipient of the patient identifying information is:

(i) A HIPAA-covered entity or business associate that has obtained and documented authorization from the patient, or a waiver or alteration of authorization, consistent with the HIPAA Privacy Rule at 45 CFR 164.508 or 164.512(i), as applicable;

(ii) Subject to the HHS regulations regarding the protection of human subjects (45 CFR part 46), and provides documentation either that the researcher is in compliance with the requirements of the HHS regulations, including the requirements related to informed consent or a waiver of consent (45 CFR 46.111 and 46.116) or that the research qualifies for exemption under the HHS regulations (45 CFR 46.104) or any successor regulations;

(iii) a member of the workforce of a HIPAA-covered entity that requires that all employer-sponsored research carried out by members of its workforce be conducted in accordance with the requirements of the HIPAA Privacy Rule (45 CFR parts 160 an 164 Subpart E) and/or the HHS regulations regarding the protection of human subjects, and has obtained and maintained the documentation referenced in paragraph (a)(1)(i) or (ii) of this section, respectively; or

(iv) subject to the FDA regulations regarding the protection of human subjects (21 CFR parts 50 and 56) and provides documentation that the research is in compliance with the requirements of the FDA regulations, including the requirements related to informed consent or an exception to, or waiver of, consent (21 CFR part 50) and any successor regulations; or

(v) any combination of a HIPAA covered entity or business associate, and/or subject to the HHS regulations regarding the protection of human subjects, and/or subject to the FDA regulations regarding the protection of human subjects, and has met the requirements of paragraph (a)(1)(i), (ii) (iii), and/or (iv) of this section, as applicable.

(2) The part 2 program or other lawful holder of part 2 data is a HIPAA covered entity or business associate, and the disclosure is made in accordance with the HIPAA Privacy Rule requirements at 45 CFR 164.512(i).

(3) If neither paragraph (a)(1) or (a)(2) of this section apply to the receiving or disclosing party, this section does not apply.

* * * * *

11. Amend § 2.53 by:

a. Revising paragraphs (a)(1)(ii), (a)(2), and (b)(2)(ii);;

b. Adding paragraph (b)(2)(iii);

c. Redesignating paragraphs (c) and (d) as paragraphs (e) and (f) respectively;

d. In newly redesignated paragraph (e)(1) introductory text, removing the reference "paragraph (c)" and adding in its place the reference "paragraph (e)";

e. In newly redesignated paragraph (e)(1)(iii), removing the reference "paragraph (d)" and adding in its place the reference "paragraph (f)";

f. In newly redesignated paragraph (e)(3)(ii)(F), removing the reference "paragraph (c)(1)" and adding in its place the reference "paragraph (e)(1)";

g. In newly redesignated paragraphs (e)(4) and (5), removing the reference "paragraph (c)(2)" and adding in its place the reference "paragraph (e)(2)";

h. In newly redesignated paragraph (e)(6), removing the reference "paragraph (c)" and adding in its place the reference "paragraph (e)";

i. Adding new paragraphs (c), (d), and (g).

The revisions and additions read as follows:

§ 2.53 Audit and evaluation.

(a) * * *

(1) * * *

(ii) Any individual or entity which provides financial assistance to the part 2 program or other lawful holder, which is a third-party payer covering patients in the part 2 program, or which is a quality improvement organization performing a QIO review, or the contractors, subcontractors, or legal representatives of such individual, entity, or quality improvement organization.

(2) Is determined by the part 2 program or other lawful holder to be qualified to conduct an audit or evaluation of the part 2 program or other lawful holder. Auditors may include any non-part 2 entity that has direct administrative control over the part 2 program or lawful holder.

(b) * * *

(2) * * *

(ii) Any individual or entity which provides financial assistance to the part 2 program or other lawful holder, which is a third-party payer covering patients in the part 2 program, or which is a quality improvement organization performing a QIO review, or the contractors, subcontractors, or legal representatives of such individual, entity, or quality improvement organization.

(iii) An entity with direct administrative control over the part 2 program or lawful holder.

(c) *Activities Included*. Audits and evaluations under this section may include, but are not limited to:

(1) Activities periodically undertaken by a federal, state, or local governmental agency, or a third-party payer entity, in order to:

(i) Identify actions the agency or third-party payer entity can make, such as changes to its policies or procedures, 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

(2) Reviews of appropriateness of medical care, medical necessity, and utilization of services.

(d) *Quality Assurance Entities Included*. Entities conducting audits or evaluations in accordance with paragraphs (a) and (b) of this section may include accreditation or similar types of organizations focused on quality assurance.

* * * * *

(g) Audits and Evaluations Mandated by Statute or Regulation. Patient identifying information may be disclosed to federal, state, or local government agencies, and the contractors, subcontractors, and legal representatives of such agencies, in the course of conducting audits or evaluations mandated by statute or regulation, if those audits or evaluations cannot be carried out using de-identified information.

12. Amend § 2.67 by revising paragraph (d)(2) to read as follows:

§ 2.67 Orders authorizing the use of undercover agents and informants to investigate employees or agents of a part 2 program in connection with a criminal matter.

* * * * *

(d) * * *

(2) Limit the total period of the placement to twelve months, starting on the date that the undercover agent or informant is placed on site within the program. The placement of an undercover agent or informant must end after 12 months, unless a new court order is issued to extend the period of placement;

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Dated: August 1, 2019.

Elinore F. McCance-Katz,

Assistant Secretary for Mental Health and Substance Use,

Substance Abuse and Mental Health Services Administration.

Approved: August 7, 2019.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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