

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

Summary of Final Rule

On July 15, 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) published in the *Federal Register* (85 FR 42986) a final rule amending its Confidentiality of Substance Use Disorder Patient Records regulations to better facilitate the exchange of information for individuals in treatment for substance use disorder (SUD).

This summary describes SAMHSA’s final provisions to update and clarify 42 CFR part 2 non-disclosure rules, reduce the burden for certain permitted disclosures, expand others, and make other miscellaneous changes. The final rule is effective August 14, 2020.

SAMHSA finalized most of the provisions as proposed but points out that Section 3221 of the recently enacted CARES Act modifies the statutory requirements for permitted disclosures of patient information for those individuals in treatment for SUD.¹ The statutory changes provide considerably more flexibility with respect to the sharing of patient records than prior law upon which these final rules are based. SAMHSA indicates that a forthcoming regulation will implement rules under the CARES Act and will likely require further modification to some of the rules finalized at this time.

SAMHSA estimates the costs of the finalized updates to part 2 to be between \$10.3 and \$11.4 in each year over the 10-year period of 2020–2029 and would total about \$104.8 million in undiscounted 2018 dollars over that period.

Table of Contents		
I.	Background and Overview of the Final Regulations	2
II.	Provisions of the Final Rule	3
	A. Definition of “Records” (§2.11)	3
	B. Applicability of Part 2 Rules to Non-Part 2 Providers (§2.12)	4
	C. Consent Requirements (§2.31)	6
	D. Disclosures Permitted with Written Consent (§2.33(b))	7
	E. Disclosures to Prevent Multiple Enrollments (§2.34)	9
	F. Disclosures to Prescription Drug Monitoring Programs (new §2.36)	10
	G. Medical Emergencies (§2.51)	10
	H. Research (§2.52)	11
	I. Audit and Evaluation (§2.53)	12
	J. Orders Authorizing the Use of Undercover Agents and Informants (§2.67)	13
III.	Collection of Information Requirements	13
IV.	Regulatory Impact Analysis	14

¹ Coronavirus Aid, Relief and Economic Security Act (“CARES Act”, P.L. 116-136)

I. Background and Overview of the Final Regulations

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

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

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

The final changes:

- Clarify that the recording of information by a non-part 2 entity about a patient treated for SUD by an entity operating a part 2 program (hereinafter referred to as a “part 2 entity”) does not, by itself, render a medical record subject to part 2 rules provided that the non-part 2 entity segregates SUD records received from a part 2 program. Changes are made to the definition of “records” to clarify when part 2 protected information is considered to be re-disclosed.
- Permit non-opioid treatment providers access to central registries and to permit opioid treatment programs (OTPs) to disclose dispensing and prescribing data to prescription drug monitoring programs (PDMPs) subject to patient consent. These changes, according to SAMHSA, will limit negative drug interactions and other potentially life-threatening consequences of poor coordination between providers prescribing drugs to those individuals with SUD.
- Allow patients to consent to disclosing part 2 treatment information for a wider range of activities without having to name each specific individual receiving that information.
- Allow disclosure of patient information to another part 2 program or SUD treatment provider during disasters without patient consent.
- Specify in regulatory text a list of examples of payment and health care operational activities for which disclosure is permitted to address stakeholder feedback that the existing rules have been confusing on these activities.

- Make amendments to audit and evaluation rules to resolve confusion about disclosures to and from governmental agencies and third-party payers among other clarifications.
- Extend the length of time that undercover agents and informants can be placed in part 2 programs.

SAMHSA received 684 public comment submissions on the proposed rule. Comments came from health care providers, third-party payers, privacy and consumer advocates, provider associations, and accrediting associations among others. Many commenters generally supported the changes while many others raised concerns that they would invade patient privacy, exacerbate the stigma of substance abuse, or deter people from seeking SUD treatment. SAMHSA disagrees with those negative consequences but notes that it will continue to consider refinements to the regulations. In response to those requesting additional clarification or educational outreach, SAMHSA notes that it has attempted to address clarifications as described below. It will consider future opportunities for guidance related to education outreach and will monitor response in the SUD treatment community for future changes as needed.

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

In response to comments related to that guidance, SAMHSA clarifies that providers should ensure that any patient communication from synced devices is also deleted from each device and that providers should ensure that the communication is forwarded to, and stored within, an authorized channel prior to deleting the communication from a personal device.

II. Provisions of the Final Rule

A. Definition of “Records” (§2.11)

SAMHSA finalizes without change its proposal to modify the definition of “records” to add to the existing definition that information conveyed orally by a part 2 program to a non-part 2 provider for treatment purposes with the consent of the patient does not, if then written down, become a record subject to part 2 rules. Non-part 2 providers can ensure that their own records do not become subject to part 2 by ensuring that records transmitted from a part 2 program to a non-part 2 provider are segregated from their own records.

Comments. Commenters expressed a concern that the changes to the definition of “records” with respect to oral communications would create an inconsistency between the treatment of those

communications and other forms of communications including texts or secure clinical messages. SAMHSA responds that the final changes will have the effect of treating oral and non-oral communications made by a part 2 program to a non-part 2 provider in the same way. Under both circumstances, a part 2 program can make a disclosure with the patient's consent to a non-part 2 provider. If that non-part 2 provider has a separate encounter with the patient, his or her records will not fall under Part 2.

Some commenters requested that oral communications between part 2 providers, non-part 2 providers and other appropriate third parties, including managed care organizations, should not require patient consent if undertaken for the purpose of treatment, payment or health operations, including care coordination and case management. SAMHSA declines to make further changes at this time, believing that the amendments finalized represent the appropriate fix for allowing a limited transfer of information between part 2 programs and non-part 2 providers, subject to patient consent, in order to facilitate better coordination of care. SAMHSA notes that it will continue to consider opportunities for further alignment of part 2 requirements for the disclosure of SUD records for treatment, payment and health care operations in the future, to the extent permissible under statute.

Those opposing the changes raised concerns that the rule change would provide a way for SUD information to be conveyed in a way that circumvents part 2 for example by using oral transcription software to transcribe full part 2 records into a non-part 2 record. SAMHSA responds that its amendments are intended to allow for a limited transfer of information between part 2 programs and non-part 2 providers. It permits a non-part 2 provider who orally receives protected SUD information from a part 2 program to subsequently engage in an independent conversation with the patient informed by the information and record that information without it becoming a part 2 record. It will not immunize the misconduct of a non-part 2 provider who engages in wholesale transcription of an SUD patient record.

A commenter asked for clarity that entities that do not deliver SUD treatment services, such as health plans and insurers, are not considered to be part 2 programs and are not non-part 2 providers. SAMHSA states that it will consider further clarifications at a later date.

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

SAMHSA finalizes without change proposed amendments to the applicability provisions of §2.12 to clarify that the records of non-part 2 entities are not covered by part 2 restrictions simply because they describe information about a patient's SUD treatment and status. The changes are consistent with the changes to the definition of "records". To confirm that the independent record-keeping of a non-part 2 provider is not subject to part 2 limitations, SAMHSA adds new subsection (d)(2)(ii) to §2.12 (which describes the applicability of the part 2 rules) to state that a non-part 2 treating provider may record information about a SUD and its treatment that identifies a patient, and this would not constitute a record that has been re-disclosed under part 2 as long as any part 2 records are segregated from the non-part 2 provider's records.

The agency describes the history of the part 2 restrictions and the need for additional clarity within the provider community about which information collected by non-part 2 entities is covered by the part 2 restrictions. Part 2 rules, as originally established, restricted the applicability of its disclosure rules only to information obtained by a federally assisted alcohol or drug abuse programs. This limited applicability to only those specialized programs was intended to limit the economic impact of the restrictions for facilities that only provided SUD treatment incident to other types of more general medical care.

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

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

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

Other conforming changes are finalized as well.

- In several places in §2.12, SAMHSA finalizes proposals to replace the use of the term “information” with the term “records.” This is to increase clarity and also to address questions from stakeholders about what is meant when rules apply to “information, whether recorded or not.”
- Under existing provisions on re-disclosure of part 2 information (§2.32) a notice is required to be provided to an entity receiving part 2 information which identifies a patient. The notice is to inform the recipient that the information is subject to the prohibition on re-disclosure and is protected under part 2. SAMHSA reacts to concerns that this notice is causing those entities or providers to manually redact portions of their data files regarding part 2 patients. SAMHSA finalizes without change, amendments to §2.32 to clarify that the recording of information about a SUD and its treatment by a non-part 2 entity is permitted and does not constitute records that have been re-disclosed under part 2.

SAMHSA notes that it considered including a proposed definition for “segmented” or “segmentation” but declined to do so out of concern that there could be unforeseen technical implications for electronic health records and health information systems. In addition, it wished to preserve maximum flexibility for providers with different capabilities to segment records, if choosing to do so, in the least burdensome way.

Comments. A number of commenters asked for more clarification of how part 2 would apply when a non-part 2 provider copies and pastes relevant information from a part-2 record, such as medications or diagnosis (or has an electronic medical record that shares such information automatically). Others requested additional guidance about when a general medical facility – for example one offering Medication Assisted Treatment – may become subject to part 2 regulations. SAMHSA will consider future guidance to help clarify these areas.

In response to commenters raising both clinical and technological concerns with segmenting patient records, SAMHSA notes that it has not changed any rules relating to segmenting records in this final regulation and that the final rules do not increase providers' burden with respect to segmenting records. It will, however, continue to monitor the field of electronic health records and continue to work on these issues.

One commenter asked how claims data that includes information about a patient's diagnosis or treatment would be impacted by this rule. SAMHSA points out that the rule is applicable to treatment and clinical records. Claims data are beyond the scope of this final rule.

With respect to clarifications to §2.32 to state specifically that only the part 2 protected record is subject to the prohibition on re-disclosure in order to prevent non-part 2 providers from redacting critical patient information, some commenters raised concerns about the difficulty in operationalizing this requirements via electronic health records and others requested additional examples and guidance for implementing re-disclosure requirements. Some commenters requested that SAMHSA consider lesser penalties for good-faith errors with respect to wrongful re-disclosures. SAMHSA states that it will work with stakeholders and provide additional guidance as needed.

C. Consent Requirements (§2.31)

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

SAMHSA has since learned that these rules have impeded patients from seeking certain types of non-medical services or benefits from governmental and non-governmental entities – such as Social Security benefits and sober living or halfway house programs – because the information cannot be shared with an entity when a patient is not able to provide a named individual as the recipient. For example, if a patient wants a part 2 program to disclose impairment information to the Social Security Administration for a determination of benefits, he is unable to do so because he cannot identify a specific individual at the agency to receive that information.

To address this problem, SAMHSA finalizes, as proposed, to amend §2.31(a)(4)(i) to permit disclosures to an *entity(-ies)* as well as to an individual(s). This general rule eliminates the need

for §2.31(a)(4)(ii). In addition, as proposed, SAMHSA amends §2.32(a)(4)(iii) (which is renumbered to be §2.31(a)(4)(ii) to clarify what is needed for patients to consent to disclosures to organizations without a treating provider relationship. The provision adds that written consents must include the names of the individual(s) or entity(ies) [instead of only the entity(ies)] to whom the disclosure is to be made.

Comments. Some commenters encouraged SAMHSA to further broaden the proposal to allow generalized consents to disclose and to re-disclose patient information for treatment, payment or health care operations. One commenter recommended that SAMHSA clarify that ACOs and health homes have a treating provider relationship and therefore would fall under the general disclosure rules. With respect to broadening the permissiveness of disclosure, SAMHSA notes that it is clarifying that disclosures can be made to entities without a treating provider relationship and will consider future revisions to broaden the requirements.

Other commenters raised concerns that amendments were too broad and could result in information being given to interconnected health care systems including unknown future entities. SAMHSA notes that a consent form must include the purpose of the disclosure and information disclosed must be limited to only that which is necessary to carry out that stated purpose.

A commenter recommended that SAMHSA expand the list of safe harbors for individuals acting in good faith to try to help an individual obtain housing, health care or other necessary services. SAMHSA indicates it will consider such changes in the future.

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

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

At this time, SAMHSA believes incorporating those examples into regulatory text would help to clarify the types of payment and operations circumstances to which §2.33(b) is intended to permit disclosures. It proposed adding the 17 examples that had been listed in the preamble to the 2018 rule to the end of existing §2.33(b). In addition to those 17 examples, SAMHSA proposed an additional 18th item to re-affirm that the list is not exhaustive.

In the final rules, SAMHSA codifies those 18 items and adds to the list another permitted example -- carrying out care coordination or case management services in support of health care payment or operations. SAMHSA notes that many commenters supported such an addition. Further, the CARES Act has expressly permitted disclosures for these purposes, so there may be future additional changes to §2.33(b) to implement the statute.

As finalized, the examples of permissible payment or health care operations activities are:

- Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing and related health care data processing;
- Clinical professional support services (e.g., quality assessment and improvement initiatives; utilization review and management services);
- Patient safety activities;
- Activities pertaining to:
 - The training of student trainees and health care professionals;
 - The assessment of practitioner competencies;
 - The assessment of provider and/or health plan performance; and/or
 - Training of non-health care professionals;
- Accreditation, certification, licensing, or credentialing activities;
- Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and/or ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care;
- Third-party liability coverage;
- Activities related to addressing fraud, waste and/or abuse;
- Conducting or arranging for medical review, legal services, and/or auditing functions;
- Business planning and development, such as conducting cost management and planning-related analyses related to managing and operating, including formulary development and administration, development or improvement of methods of payment or coverage policies;
- Business management and/or general administrative activities, including management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations;
- Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;
- Resolution of internal grievances;
- The sale, transfer, merger, consolidation, or dissolution of an organization;
- Determinations of eligibility or coverage (e.g., coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;
- Risk adjusting amounts due based on enrollee health status and demographic characteristics;
- Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;
- Care coordination and/or case management services in support of payment or health care operations; and
- Other payment/health care operations activities not expressly prohibited.

Comments. Some commenters requested additions to the list or that SAMHSA provide specific examples of permitted activities. SAMHSA declines more additions or examples indicating that the broad language provides flexibility for stakeholders to carry out necessary activities.

In response to a commenter asking for clarity about when written consent is required, SAMHSA replies that the activities listed in §2.33(b) require a patient's consent. However, it notes that under §2.12(c)(3), restrictions on disclosures in part 2 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 SUDs 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.

A few commenters raised concerns that the broadly described activities could permit disclosures that could harm patients, for example by allowing protected SUD information to be disclosed to employers. SAMHSA describes some of the provisions in part 2 that may help to limit those types of disclosures. In response to commenters who requested that SAMHSA clarify the circumstances under which an ACO can use disclosed part 2 information, the agency stated that the use of such information by a provider with a treating provider relationship should be sufficiently broad to cover the patient's care team within an ACO and that it will consider additional guidance on this question in the future. To commenters requesting that SAMHSA fully align the part 2 rules with HIPAA, the agency points out that the authorizing statute is more stringent than HIPAA standards.

E. Disclosures to Prevent Multiple Enrollments (§2.34)

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

Under prior rules, however, a central registry could only disclose such information when asked by a "member program" about a patient's enrollment in another program. SAMHSA finalizes without change its proposal to expand the scope of this permitted disclosure so that non-OTP providers with a treating provider relationship may query a central registry to determine if their patient is already receiving opioid treatment.

Comments. In response to concerns that the proposal will reduce patient privacy, SAMHSA replies that it remains dedicated to protecting information for individuals with SUD but that doing so cannot come at the cost of patient safety. To those concerned about the concept of central registries more generally, SAMHSA points out that those registries already exist within OTPs and states and that the proposed and final rules do not compel patients with SUD to register on any lists. In addition, it points out that any non-OTP providers querying the list must demonstrate a treating provider relationship. Some commenters recommended that SAMHSA establish minimum standards for central registries or consider using health information exchanges to coordinate queries to the registries. SAMHSA states that it will consider those suggestions in future rules and guidance.

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

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

In light of the public health crisis presented by the opioid epidemic, SAMHSA finalizes without change, its proposal to permit OTPs to report SUD medications prescribed or dispensed to the applicable state PDMP with the written consent of the patient. It expects that with the addition of the OTP data, fewer adverse events, duplicate or contraindicated prescriptions, overdoses, or other fatal drug interactions will occur.

Comments. A number of commenters raised concerns about privacy, misuse of PDMP data by law enforcement or for occupational health purposes, and lack of interoperability between PDMPs and electronic health records. Others recommended that SAMHSA establish minimum standards or require the use of health information exchanges to coordinate queries to PDMPs. SAMHSA points out that PDMPs are established and overseen by states so SAMHSA does not govern their operation, but it reiterates that allowing OTP reporting to PDMPs could enhance their use as a tool to help prevent prescription drug misuse and opioid overuse.

G. Medical Emergencies (§2.51)

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

SAMHSA finalizes its proposal without change to add to this section to permit such disclosures without a patient’s consent in the case of natural and major disasters. SAMHSA notes that disasters such as hurricanes and wildfires can interrupt the usual access to services and medications, requiring patients to seek treatment in facilities or with providers who do not have full access to their records. This change permits treatment to continue under such circumstances.

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

Comments. Several commenters asked about the scope of the regulatory change and how the exception would work including whether it applies to all patients in an emergency area whose part 2 programs have closed, whether the closed part 2 program determines if it is a medical emergency for the patient, and whether there is an explicit start and end to such situations. SAMHSA replies that if a patient’s part 2 program has closed and is unable to provide services

or obtain the written consent of the patient due to a state of emergency caused by a natural or major disaster, then that part 2 program may disclose part 2 patient records to other medical personnel to deliver effective ongoing SUD services. SAMHSA notes that the health care or provider treating the medical emergency would determine which personnel are needed to treat the individual and can make a determination that a medical emergency is taking place. SAMHSA reiterates that consent should still be obtained if at all feasible.

H. Research (§2.52)

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

SAMHSA has become aware that certain researchers, such as state agencies, do not fall under either of those permitted disclosures. In order to more closely align with the research disclosures permitted under the HIPAA Privacy Rule and the Common Rule, SAMHSA finalizes its proposal to modify §2.52(a) to allow research disclosures of part 2 data from a HIPAA-covered entity or business associate to individuals and organizations who are neither HIPAA-covered entities, nor subject to the Common Rule, provided that any such data will be disclosed in accordance with the HIPAA Privacy Rule at 45 CFR 164.512(i). This change would, according to SAMHSA, align the requirements of part 2 with the HIPAA Privacy Rule around the conduct of research on human subjects.

SAMHSA proposed two additional changes to §2.52(a) but finalizes only one of those changes.

With respect to its proposal to clarify that research disclosures may be made to members of the workforce of a HIPAA-covered entity for purposes of employer-sponsored research, SAMHSA described confusion as to what was meant by "employer-sponsored research." Commenters interpreted such research to refer to research conducted by employers on or about their employees. SAMHSA indicates that that was not its intent and declines to finalize the proposal because of that confusion.

The proposal to permit research disclosures without consent to recipients who are covered by FDA regulations for the protection of human subjects in clinical investigations is finalized as proposed except it would be new §2.52(a)(1)(iii) instead of (iv).

Comments. One commenter raised the concern that the additional flexibility available for research disclosures does not permit disclosures for public health analysis and requested that SAMHSA be explicit in permitting the release of data to a state or state data repository for the purpose of public health research. SAMHSA replies that the changes permit disclosure for research purposes to a state so long as it is in accordance with the HIPAA privacy rule and notes that the research exception has been further broadened under the CARES Act to specifically permit disclosures with or without consent of de-identified data to a public health authority. It expects to issue new rulemaking to implement that provision of the CARES Act.

I. Audit and Evaluation (§2.53)

SAMHSA proposed a number of additions to existing rules related to permitted disclosures for audit and evaluation purposes intended to clarify allowable evaluation activities. The proposed amendments are finalized with several changes as described below.

Under prior rules, if the requirements in §2.53 were met, information could be disclosed to individuals and entities who perform audits or evaluations on behalf of governmental agencies that provide financial assistance to a part 2 program or have regulatory authority over it, a third-party payer for coverage of part 2 patients, an individual or entity which provides financial assistance to a part 2 program, or a quality improvement organization (QIO) performing utilization or quality control review and for Medicare, Medicaid, or CHIP audits or evaluations. There has been, however, continuing confusion about the applicability of the audit and evaluation provisions under specific circumstances in part due to the absence of a definition of audit and evaluations.

SAMHSA finalizes its proposals with several changes to clarify the uses of patient data for audit and evaluation and finalizes those clarifications with several changes in the final rule as described below. SAMHSA:

- Clarifies that auditors can include a non-part 2 entity that has direct administrative control over the part 2 program.
- Clarifies that audits and evaluations permitted under this section include:
 - Activities undertaken by a federal, state, or local governmental agency, or a third-party payer entity to (i) Identify actions the agency or third-party payer entity can make to improve care and outcomes for patients with SUD that are treated by 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. The proposed rule described these activities as “periodically” undertaken. In response to comment that by including that term, flexibility for entities with administrative control or third-party payers to determine the appropriate frequency of audit and evaluation activities would be reduced. As a result, SAMSHA eliminated the word “periodically”. Final language intended to enable audits or evaluations for the purposes of improving care and outcomes was also altered to remove “across part 2 programs” at the end of the phrase. Commenters felt that could be interpreted to mean that those activities could only be conducted within part 2 programs which would be a more narrow interpretation than was intended.
 - Reviews of appropriateness of medical care, medical necessity, and utilization of services. In response to commenters who raised concerns that expanding the scope of audits or evaluations to include reviews of appropriateness, medical necessity, and utilization will result in such audits or evaluations being used to restrict access to SUD treatment, SAMHSA adds language in the final rule to clarify that its intent is to permit evaluations to enhance patient care and coverage.
- Clarifies that quality assurance entities that conduct audits or evaluations under this section may include accreditation organizations or other similar organizations that are focused on quality assurance. Existing rules specifically permit disclosure to QIOs, but

this provision would ensure that other types of entities such as accrediting or certification bodies may use such disclosures as well.

- Ensures that if de-identified data are not available, audits and evaluations that are mandated by statute or regulation have access to patient identifying information.
- Makes technical changes aligning language related to quality improvement organizations so that it conforms to current QIO regulations.

Comments. In response to a commenter who continues to find the term “evaluation” to be unclear, SAMHSA states that it believes that the concept of audit or evaluation at least includes reviews that examine individual part 2 program clinical and or financial performance and reviews to determine if there are any needed actions to improve care or outcomes. SAMHSA will consider for future rulemaking, as requested by a commenter, requiring third parties conducting audits on behalf of an agency or organization to provide a copy of its contract to ensure it is a legitimate investigation. It also encourages part 2 programs and third parties to consider using copies of the contracts for that purpose as well.

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

Under prior rules, undercover agents and informants could be placed in a part 2 program for a total of 6 months. That period could have been extended only by a court order. SAMHSA determined that since a typical undercover operation can often last longer than 6 months, it proposed extending that period to 12 months. In addition, the 12-month period would begin when an undercover agent is placed or an informant is identified in the part 2 program. The provisions are finalized as proposed.

Comments. Commenters raised concerns that permitting the presence of undercover officers and informants in part 2 programs would deter individuals from seeking treatment and would be a violation of ethics, privacy, and constitutional rights. Others felt that the changes could permit these rules to become used as a tool of prosecution instead of recovery. SAMHSA cites the existing safeguards that it believes will prevent undercover agents and information from misusing the placements.

III. Collection of Information Requirements

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

- Disclosures to state PDMPs in states in which such disclosures are required could result in a total cost burden \$4.1 million including both the costs in year 1 of an initial update of the PDMP database and the costs of annual reporting.
- Additional disclosures may occur during natural and major disasters, for research purposes, and for audits and evaluations. SAMHSA estimates that altogether the additional disclosures could result in a cost burden of \$7.0 million.

Together the additional burden for year one is estimated to be equal \$11.2 million.

IV. Regulatory Impact

SAMHSA estimates the costs of the proposed amendments to 42 CFR part 2 would largely be the collection of information burden as discussed above. Altogether those costs would be between \$10.3 and \$11.4 million in each year over the 10-year period of 2020–2029 and would total about \$104.8 million in undiscounted 2018 dollars over that period. It also provides those 10-year estimates at an annual discount rate of 3% (\$89 million) and 7% (\$74 million).