

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Part 2

[SAMHSA–4162–20]

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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: Final rule.

SUMMARY: This final rule makes changes to the Department of Health and Human Services' (HHS) regulations governing the Confidentiality of Substance Use Disorder Patient Records. These changes 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 SUD care, while addressing the legitimate privacy concerns of patients seeking treatment for a SUD. Within the constraints of the authorizing statute, these changes are also an effort to make the regulations more understandable and less burdensome.

DATES: This final rule is effective August 14, 2020.

FOR FURTHER INFORMATION CONTACT: Ms. Deepa Avula, (240) 276–2542.

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Acronyms

- ADAMHA Alcohol, Drug Abuse, and Mental Health Administration
- CEHRT Certified Electronic Health Record Technology
- 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
- FHIR Fast Healthcare Interoperability Resources
- FR Federal Register
- HHS Department of Health and Human Services
- HIPAA Health Insurance Portability and Accountability Act of 1996
- HIE Health Information Exchange
- HIN Health Information Network
- IHS Indian Health Service
- MAT Medication-Assisted Treatment
- NPRM Notice of Proposed Rulemaking
- ONC Office of the National Coordinator for Health Information Technology
- OTP Opioid Treatment Program
- ODD Opioid Use Disorder
- PDMP Prescription Drug Monitoring Program
- QIO Quality Improvement Organization
- TPO Treatment, Payment, and Health Care Operations
- 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 U.S.C. 290dd–2. The regulations were originally issued to ensure the confidentiality of patient records for the treatment of substance use disorder, at a time when there was no broader privacy and data security standard for protecting health care 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 new laws and regulations implemented since 1975, that more broadly protect patient data. At the same time, consistent with the authorizing statute, we (note that throughout this final rule, “we” refers to SAMHSA) wished to preserve the confidentiality protections that part 2 establishes for patient identifying information originating from covered programs, because persons with SUDs 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 SUD 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 SUDs 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 SUD 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.² On August 26, 2019, SAMHSA published a Notice of Proposed Rulemaking (NPRM) (84 FR 44568) that proposed changes to the part 2 regulations that SAMHSA believed 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, while ensuring appropriate confidentiality protection for persons in treatment through part 2 programs.

SAMHSA requested public input of the proposed changes during a 60-day public comment period.

¹ Mortality statistics published by the Centers for Disease Control and Prevention reflected a spike in the rate of opioid-related overdose deaths during the period from 2013–2017. See https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w. More recent data from the State Unintentional Drug Overdose Reporting System (SUDORS), showed that opioid-involved overdose deaths in 25 states slightly decreased from July–December 2017 to January–June 2018. However, even in that time period, increases in illicitly-manufactured fentanyl overdose deaths involving multiple drugs almost negated decreases in fentanyl analog deaths and prescription opioid-involved overdose deaths. See <https://www.cdc.gov/mmwr/volumes/68/wr/mm6834a2.htm>.

² With regard to heightened demand for, and pressures upon, SUD treatment services in the opioid epidemic, see for example, “HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis,” Department of Health and Human Services, October 26, 2017 (at <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html>); “Today’s Heroin Epidemic: More People at Risk, More Drugs Abused,” Centers for Disease Control and Prevention, July 7, 2015 (at <https://www.cdc.gov/vitalsigns/heroin/>).

After consideration of the public comments received in response to the NPRM, SAMHSA is issuing this final rule substantially as proposed, with one caveat. On March 27, 2020, President Trump signed the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) into law (Pub. L. 116–136). The CARES Act was enacted to provide emergency assistance to individuals, families and businesses affected by the COVID–19 pandemic; to support the U.S. health care system; and to make emergency appropriations to the Executive Branch. Section 3221 of the CARES Act, Confidentiality and Disclosure of Records Relating to Substance Use Disorder, substantially amended several sections of the part 2 authorizing statute; specifically, sections 42 U.S.C. 290dd–2(b), (c) and (f), which specify requirements for patient consent, restrict the use of records in legal proceedings, and set penalties for violations of the statute, respectively.³ The CARES Act provides far greater flexibility for patients and health care providers to share SUD records than presently allowed under 42 U.S.C. 290dd–2. Most notably, some sections in the new statute seek to align the part 2 confidentiality standards more closely with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The CARES Act requires HHS to update its regulations to implement these new statutory changes; therefore, HHS intends to publish a new NPRM and subsequently to issue a new final implementing rulemaking for the CARES Act in the future. Because both Congress and SAMHSA have sought to address many of the same barriers to information sharing by patients and among health care providers, we expect that the CARES Act implementing regulations will further modify several of the amendments adopted in this final rule.

The statutory timeline in § 3221 prevents the part 2-related provisions of the CARES Act from taking effect before March 27, 2021. In the interim, we believe that this final rule makes important changes that can help safeguard the health and outcomes of individuals with SUD, and specifically takes important first steps toward the greater flexibility for information sharing envisioned by Congress in its passage of § 3221 of the CARES Act. Thus, several of the regulatory amendments in this final rule will serve

³ Section 3221 of the CARES Act also added several new provisions to the Part 2 authorizing statute, codified at 42 U.S.C. 290dd–2(i), (j), and (k), regarding antidiscrimination, notification of breach and definitions, respectively.

as interim and transitional standards, until regulations conforming to the CARES Act legislation can be promulgated.

II. Summary of the Major Provisions

Proposed modifications to 42 CFR part 2 were published as an NPRM on August 26, 2019 (84 FR 44568). After consideration of the public comments received in response to the NPRM, SAMHSA is issuing this final rule as follows:

Definitions (§ 2.11) revises the definition of “Records” to create an exception so that information conveyed orally by a part 2 program to a non-part 2 provider for treatment purposes with consent of the patient does not become a record subject to part 2 regulations merely because that part 2 information is reduced to writing by that non-part 2 provider.

Applicability (§ 2.12) revises the regulatory text to state that the recording of information about an SUD and its treatment by a non-part 2 provider does not, by itself, render a medical record subject to the restrictions of 42 CFR part 2, provided that the non-part 2 provider segregates any specific SUD records received from a part 2 program (either directly, or through another lawful holder).

Consent requirements (§ 2.31) revises consent requirements to allow patients to consent to the disclosure of their information to a wide range of entities without naming a specific individual to receive this information on behalf of a given entity, and includes special instructions applicable to consents for disclosure of information to information exchanges and research institutions. The final rule provides additional guidance, with regard to consent for disclosures for the purpose of care coordination and case management.

Prohibition on redisclosure (§ 2.32) revises the prohibition on redisclosure notices to clarify that non-part 2 providers do not need to redact information in a non-part 2 record regarding SUD and allows re-disclosure if expressly permitted by written consent of the patient or permitted under part 2 regulations.

Disclosures permitted with written consent (§ 2.33) expressly allows disclosure to specified entities and individuals for 18 types of payment and health care operational activities, including the 17 proposed activities and the addition of disclosures for the purpose of care coordination and case management.

Disclosures to prevent multiple enrollments (§ 2.34) revises disclosure requirements to allow non-opioid

treatment providers with a treating provider relationship to access central registries.

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

Medical Emergencies (§ 2.51) authorizes disclosures of patient information to another part 2 program or other SUD treatment provider during State or Federally-declared natural and major disasters.

Research (§ 2.52) permits research disclosures of part 2 patient data by a HIPAA covered entity to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule, for the purpose of conducting scientific research. The revised § 2.52 better aligns the requirements of part 2, the Common Rule, and the Privacy Rule around the conduct of research on human subjects, and seeks to streamline duplicative requirements for research disclosures under part 2 and the Privacy Rule in some instances. This final rule also revises § 2.52 to permit research disclosures to recipients who are covered by Food and Drug Administration (FDA) regulations for the protection of human subjects in clinical investigations (at 21 CFR parts 50 and 56).

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

Orders authorizing use of undercover agents and informants (§ 2.67) amends the period for court-ordered placement of an undercover agent and informant within a part 2 program to 12 months and clarifies that the 12-month time period starts when an undercover agent

or informant is placed in the part 2 program.

Use of Personal Devices and Accounts

This final rule preamble also provides 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 employment in the part 2 program, and this part 2 program is discontinued, then 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, we recognize that patients may make contact through the personal device or account 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.⁴ 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.

Following the proposed rule, SAMHSA received the following comments on its guidance concerning how employees, volunteers and trainees of part 2 facilities should handle communications using personal devices and accounts.

Public Comments

Many commenters supported the clarification on sanitizing personal devices. A few commenters noted that while this change will require education and monitoring, the clarification is important and valuable for part 2 programs to properly handle patient communication. Some commenters also noted that this clarification reduces burden for providers in rural areas where communication on authorized channels may not always be available.

SAMHSA Response

We appreciate comments in support of this clarification.

Public Comments

Some commenters had additional questions regarding the use of personal devices. One commenter requested guidance pertaining to the sanitizing of any other devices synchronized (“synced”) to personal accounts. A few commenters requested clarification as to whether deleting content from a personal account contravenes any state record retention requirements. One commenter requested clarification that this guidance applies only to personal devices, not professional devices from which EHRs are accessed. One commenter requested that “incidental” communication be defined more clearly. One commenter suggested that the rise of personal devices and changing nature of communication with patients may

⁴ When the circumstances requiring a response from the employee’s account due to the best interest of the patient have ended or otherwise permit, the messages should be forwarded to an authorized channel (if containing patient identifying information) and deleted.

warrant greater consideration from SAMHSA in future rulemaking.

SAMHSA Response

We appreciate questions from commenters to further clarify the use of personal devices. Providers should ensure that any patient communication accessible from synced devices is deleted from each device. Additionally, if a patient communication is contained solely on a personal device, providers should ensure that the communication is forwarded to and stored within an authorized channel prior to deleting the communication from the personal device. Providers concerned about state record retention requirements may include a note that the information has been forwarded to and stored within an authorized channel and deleted in compliance with 42 CFR part 2; however, this rule does not preempt more restrictive state record retention requirements. Given that the definition of what constitutes incidental communication varies for providers in different settings (e.g., rural), we decline to further define the phrase at this time. We appreciate the suggestion to further consider personal devices and will continue monitoring the issue.

The other sections in 42 CFR part 2 that are not referenced above are not addressed in this final rule nor were they discussed in the NPRM because SAMHSA is maintaining their content substantively unchanged from the 2017 and 2018 final rules.

III. Overview of Public Comments Received

SAMHSA received 684 public comment submissions on the proposed rule from medical and behavioral health care providers; combined medical/behavioral health care providers; third-party payers; privacy/consumer advocates; medical health care provider associations; behavioral health care provider associations; accrediting organizations; researchers; individuals (with no stated affiliation); attorneys (with no stated affiliation); health information technology (HIT) vendors; and state/local governments. The comments ranged from general support or opposition to the proposed provisions, to specific questions or comments regarding the proposed rules.

Some comments were outside the scope of or inconsistent with SAMHSA's legal authority regarding the confidentiality of SUD patient records. Likewise, other comments did not pertain to specific proposals made by SAMHSA in the NPRM. In some instances, commenters raised policy or operational issues that are best

addressed through sub-regulatory guidance that SAMHSA will consider issuing subsequent to this final rule. Consequently, SAMHSA did not address these comments in this final rule.

IV. Final Modifications to 42 CFR Part 2 and Discussion of Public Comments

In this section of the final rule, SAMHSA explains the finalized revisions to the part 2 regulations and responds to public comments received. If a 42 CFR part 2 section is not addressed below, it is because SAMHSA did not propose changes to that part 2 provision and this final rule maintains the existing language in that section.

A. General Comments on the Proposed Rule

1. General Feedback on the Proposed Rule

a. General Support for the Proposed Rule

Public Comments

Many commenters expressed general support for the proposed rule. Among them, many believed that providers will be better able to offer a fully integrated model of care as a result, thereby allowing SUD services to be accessed more seamlessly, while increasing access to critically-needed SUD treatment. Other commenters expressed general support for the proposed rule because they saw it as protecting patient privacy, while making electronic health information sharing less burdensome and more efficient. Another set of commenters articulated support for SAMHSA's efforts to balance privacy protections with advances in the health care delivery system. Some commenters who expressed broad support for the proposed rule also suggested that HHS should carry out a comprehensive assessment of how well all the HHS patient privacy rules are currently working. A few commenters who expressed support for the proposed rule also expressed concern that it might not be flexible enough to support the rapid pace of care coordination that is needed to improve SUD patient care.

SAMHSA Response

SAMHSA appreciates the support for updating the part 2 regulations. This final rule is intended to modernize part 2 by continuing to align the regulations with advances in the U.S. health care delivery system. In general, SAMHSA aims to facilitate information exchange for safe and effective SUD care, while addressing the legitimate privacy concerns of patients seeking treatment for a SUD. But 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, as well as correspondingly greater pressures on the SUD treatment system, and heightened demand for SUD treatment services. This final rule implements changes that SAMHSA believes will better align the needs of individuals with SUD and of the providers who treat them, thereby facilitating the coordination of care, while ensuring appropriate confidentiality protection for patients. SAMHSA will continue to monitor part 2 and its impact on both persons with SUD and providers, and will likewise continue to consider opportunities for further refinement of the rule in alignment with the provisions set forth in the CARES Act.

b. General Opposition to the Proposed Rule

Public Comments

Many commenters opposed the proposed rule, either without stating a specific reason, or else expressing that the proposed rule would constitute an invasion of patient privacy generally, or of their own personal privacy in particular. Many commenters opposed the rule on the grounds that it would exacerbate the stigma of substance use disorder, increase the potential for law enforcement access to patient records, deter people from seeking SUD treatment, and/or result in harm to SUD patients in several other ways, as through discrimination by health insurers. A different group of commenters expressed a competing concern about continuing administrative, financial and clinical barriers to better SUD care, and more effective coordination of care, under the proposed rule. Several of these commenters said that they believed the barriers could continue to endanger the safety of patients.

SAMHSA Response

SAMHSA wants to ensure that persons with SUD will have access to treatment services that include better coordination of care, and that deliver better quality of care and enhanced patient safety, while continuing to respect the legitimate privacy concerns of patients. The current final rule is consistent with this aim, and with the intent of the governing statute (42 U.S.C. 290dd-2) and regulations at 42 CFR part 2, which is to facilitate entry into SUD care by protecting the confidentiality of SUD patient records. SAMHSA believes that this final rule reflects an appropriate balancing of interests

toward achieving these ends. SAMHSA does not believe that this final rule will generally exacerbate stigma for persons with SUD, deter them from seeking treatment, or lead to other broadly negative downstream effects. SAMHSA will continue to consider opportunities for future refinements to the part 2 regulations, consistent with the provisions of the CARES Act.

c. General Request for Clarification and Guidance Related to Part 2

Public Comments

Several commenters broadly requested that SAMHSA provide clarification and guidance, in connection with confusing language and complexity in the proposed rule. Many other commenters said that educational outreach and guidance should be targeted to providers, to ensure that they understand the terms of the proposed rule.

SAMHSA Response

SAMHSA has provided further clarification through its responses to public comments in several sections of the final rule. SAMHSA recognizes the need for educational outreach both to persons with SUD and to providers in connection with the final rule, and is considering opportunities for further guidance and for carrying out related educational outreach. SAMHSA will continue to monitor the response to part 2 in the SUD treatment community, and will consider future refinements and further clarification to the part 2 rules as needed.

2. General Comments on Realigning the Part 2 Rule to the HIPAA Privacy Rule

Public Comments

Many commenters offered broad feedback that the privacy rules of 42 CFR part 2 are cumbersome and should be re-aligned with the HIPAA privacy rule. The commenters asserted that doing so could strengthen patient protections while allowing clinicians access to patient information needed to ensure patient safety and provide quality care. In a related vein, other commenters expressed support for legislation already introduced in Congress, aimed at more fully aligning the confidentiality standards of 42 CFR part 2 with the HIPAA privacy rule.

SAMHSA Response

SAMHSA noted the many comments that requested that SAMHSA align part 2 provisions with HIPAA where possible. In some instances, SAMHSA has attempted to do so in this final rule, to the extent that such changes were

permissible under 42 U.S.C. 290dd–2. At the same time, part 2 and its governing statute are separate and distinct from HIPAA and its implementing regulations. Because of its targeted population, part 2 does establish more stringent federal protections than most other health privacy laws, including HIPAA.

Consistent with general comments about alignment of this regulation with HIPAA, SAMHSA has modified the definition of “records” (§ 2.11) and the applicability section (§ 2.12) to facilitate the disclosure of records from part 2 programs to non-part 2 providers for treatment purposes, while allowing the non-part 2 providers to engage in their own clinical encounters and record-keeping without fear that those activities will be subject to part 2. In addition, SAMHSA has offered revised guidance concerning the part 2 consent requirements (§ 2.31), in order to more explicitly allow patients to consent to disclosure of their records for the purpose of care coordination. As discussed below, SAMHSA is also modifying the regulatory text in § 2.33(b), to include disclosures for the purpose of care coordination and case management to the list of permitted activities. All these revisions will have the effect of more closely aligning confidentiality standards under part 2 with the HIPAA privacy rule.

As previously noted, on March 27, 2020, the President signed the CARES Act into law, and § 3221 of the CARES Act makes a significant modification to the authorizing statute for part 2, with the aim of realigning the part 2 rules more strongly with the HIPAA privacy rule. HHS anticipates releasing a new proposed rule within the next 12 months to implement § 3221 of the CARES Act. In the meantime, several of the regulatory amendments in this final rule will serve as transitional standards, until regulations fully conforming to the CARES Act legislation can be promulgated.

B. Definitions (§ 2.11)

SAMHSA is finalizing this section as proposed.

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); we, 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 section III.B. of the proposed rule [84 FR 44571] on “Applicability” (at § 2.12), SAMHSA discussed 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 change was needed to facilitate communication and coordination between part 2 programs and non-part 2 providers, and to ensure that appropriate communications were 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 proposed to make a conforming amendment to the § 2.11 definition of “records,” [84 FR 44571] 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 the proposed amendment was to incorporate a very limited exception to the definition of “records,” such that a non-part 2 provider who orally receives information from 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. The intent of this change was 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.

The comments we received on the proposed amendments to § 2.11, and our responses, are provided below.

Public Comments

Many commenters supported the proposed change to the definition of records, saying that it would provide clarification as to which records are subject to part 2 protections; enable providers to take account of the entirety of a patient's health needs when determining a treatment plan; improve care coordination, especially among those with multiple medical concerns; better integrate primary and behavioral care for SUD patients; enhance patient safety; and potentially incentivize clinicians to treat patients with SUD. One commenter said the proposed definition of a record may be the most beneficial proposal in the rule, and noted that SAMHSA retains in its proposals the necessary protections against redisclosure by downstream recipients of part 2 records absent explicit patient consent. Another commenter expressed a desire to have more flexibility for care coordination across their delivery system for SUD patients, and observed that any changes to the definition of records requires balancing the need for increased protection for SUD treatment information with the need for access to care coordination.

SAMHSA Response

We thank the commenters for their support and reflections.

Public Comments

Several commenters supported the proposal but asked that SAMHSA expand the proposal beyond information conveyed orally to cover other forms of communications, including secure clinical messages (such as a secure web portal), which are common ways for providers to share information. One commenter said it would be confusing to allow orally communicated information to be covered under HIPAA while the same information conveyed via text would retain part 2 requirements. Other commenters said that imparting the oral requirement fails to appreciate workflow; that secure messaging is just as critical for patient safety; and that if information is received through electronic means, such as a Health Information Exchange, it should not become a record subject to part 2 if the non-part 2 provider includes it in his/her record.

A few commenters recommended that SAMHSA remove the word "orally" altogether from the proposed definition of records, to enable non-part 2 providers to document critical information received from a program

regardless of the manner and mode in which it is provided. A few commenters suggested that non-part 2 providers should be allowed to document information such as medications if that information constitutes redisclosure with other providers for treatment purposes, without penalty hinging on whether the information is conveyed orally or by other means.

Others encouraged SAMHSA to provide greater emphasis on the ways that health information can be shared, used, and disclosed for the benefit of individuals' treatment, payment processes, and health care operations, and to further align definitions in the future such that part 2 providers could share pertinent information with non-part 2 providers.

SAMHSA Response

Although the change to the definition of "records" under § 2.11 applies to information disclosed orally by a part 2 program to a non-part-2 provider, this change will not create a disconnect under part 2 with regard to how other forms of communication by a part 2 program are treated. More specifically, the changes in § 2.12 of the rule on "Applicability" establish that records containing SUD information about a patient created by a non-part 2 provider will not be covered by part 2, unless any SUD record previously received from a part 2 program is incorporated into such records. Under § 2.12, segregation of the received record can be used by non-part 2 providers to ensure that their own created patient records can be distinguished from the received record, and thus will not become covered by part 2.

Taken together, the effect of the revisions to §§ 2.11 and 2.12 is to cause both oral and non-oral communications made by a part 2 program to a non-part 2 provider to be treated in the same way under the regulations. In each instance, the intent is to allow the part 2 program to make a disclosure, with the patient's consent, to the recipient non-part 2 provider. In turn, the non-part 2 provider can then carry out her own encounter with the patient, and create her own patient record, which will not fall under the coverage of part 2. Again, segregation of any received SUD record may be used by a non-part 2 provider to ensure that her own created records can be distinguished, and will therefore not become subject to part 2.

SAMHSA recognizes the importance of secure messaging and other forms of electronic communication and record-keeping in SUD care. SAMHSA nevertheless believes that the current revisions to §§ 2.11 and 2.12 offer an

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 will continue to consider opportunities for further re-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 the part 2 enabling statute, and in alignment with the provisions of § 3221 of the CARES Act.

Public Comments

One commenter requested that SAMHSA revise the definition of records to allow for oral communication between relevant entities without obtaining patient consent. The commenter said that requiring the consent of the patient in this instance is contrary to the stated intent of facilitating care coordination, and that SAMHSA should clarify that conversations 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. Another commenter recommended exempting information about medications and laboratory results from the definition of "records," thereby making it possible for a part 2 program to disclose such information without patient consent. That commenter asserted that such an exemption would help to enable a patient's [non-part 2] treatment providers to monitor for abuse, medication-seeking behavior, drug interactions, and possible diversion.

SAMHSA Response

SAMHSA believes that the current revisions to §§ 2.11 and 2.12 offer an 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. Other forms of communication between lawful holders of part 2 records are also permitted under the part 2 regulations with patient consent, consistent with the enabling statute. The revisions to §§ 2.11 and 2.12 reflect a balance of interests between ensuring robust privacy protection for part 2 program treatment records, while also pursuing patient safety, reduction of adverse events, and better coordination of care for persons with SUD. As discussed below, SAMHSA is also modifying the

regulatory text in § 2.33(b), to include disclosures for the purpose of care coordination and case management to the list of permitted activities. SAMHSA will continue to consider opportunities for further re-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 the part 2 enabling statute and in alignment with § 3221 of the CARES Act.

Public Comments

One commenter urged SAMHSA to further update the definitions of part 2 to make it clear that entities that are not directly delivering SUD treatment services, such as health plans and insurers, are explicitly not part 2 programs and are not non-part 2 providers. The commenter believes that making this concept more explicit would clarify confusion as to whether records created by health plans and insurers, independent of information disclosed to the health plan or insurer by a part 2 provider, are subject to part 2.

SAMHSA Response

SAMHSA appreciates this comment. Although outside the scope of the current rulemaking, SAMHSA will consider further clarifications to the definition of “part 2 program” in the future.

Public Comments

A few commenters expressed concern that the proposed revision to § 2.11 may create an over-reliance upon oral communication and transcription, which they believe is inherently less accurate than electronic sharing of records; may further fragment patient records; and may encourage providers to avoid using electronic health records, especially for certain SUD information. Another commenter stated that the proposed exception for oral communications will prove difficult for part 2 programs and treating providers. The commenter said that compliance, privacy, and legal advisors will be hesitant to permit part 2 program staff to communicate with other health care providers orally due to concerns about misunderstandings or inaccurate transcriptions of oral communications, especially if there is no written record. Several commenters encouraged SAMHSA to recognize the need for accurate, complete, and efficient electronic exchange of information, such as through the new interoperable electronic health records that CMS and ONC seek to promote with their recent

rulemaking, and move away from paper charts and manual faxing.

SAMHSA Response

Although the change to the definition of “records” under § 2.11 applies to information communicated orally by a part 2 program to a non-part-2 provider, this change will not result in a disconnect under part 2 with regard to how other forms of disclosure by a part 2 program are treated. Rather than creating a new reliance on oral communications over other methods of sharing records, SAMHSA believes that the change in §§ 2.11 and 2.12 will have the opposite effect, by making it more clear how a non-part-2 provider can receive and segregate an electronic or paper record from a part 2 program, without incurring the risk that any subsequent patient records directly created by the recipient provider will then become covered by part 2. For example, in the context of receiving an electronic part 2 record, such as a summary of care document, shared between interoperable EHR systems that meet DS4P standards, “segregation” might be carried out by segmenting the received SUD record so as to preserve the recipient’s ability not to disclose it based on the sensitivity of its content. SAMHSA has been collaborating with both ONC and CMS in connection with their rulemaking efforts on the interoperability of electronic healthcare records, to ensure that health IT policies consider the impacts for part 2 providers and vice versa.

Public Comments

One commenter recommended that SAMHSA devote resources toward ensuring that patients understand the implications of the new policy. The commenter stated that when a patient consents to the release of a part 2 record to a non-part 2 provider, he or she must understand that they are not simply consenting to use of the information for a one-time conversation with the non-part 2 provider, but rather they are consenting to the information potentially becoming a part of his or her main medical record. The commenter believes that both the part 2 provider and the non-part 2 provider should make this clear, or else it could have a significant chilling effect on patients seeking SUD treatment, as those patients may believe that their right to confidentiality has been removed.

SAMHSA Response

SAMHSA appreciates this comment. We are considering opportunities for further guidance and patient and

provider education, in connection with the new part 2 rule.

Public Comments

Several commenters opposed the changes proposed in the revised § 2.11. Some commenters explicitly opposed excluding from the definition of “records” any oral communication from a part 2 program that is received and later reduced to writing by a non-part 2 provider. These commenters said the ability to transmit SUD information orally would circumvent part 2, because the information would thereby lose its protection, and that patients who consent to sharing their records with a non-part 2 provider will not understand that information shared orally is not protected by part 2 in the recipient provider’s records.

SAMHSA Response

Although the change to the definition of “records” under § 2.11 does apply to information communicated orally by a part 2 program to a non-part-2 provider, this change will serve to clarify, rather than to modify, the application of part 2 to patient records created by downstream non-part 2 providers. Neither the enabling statute, nor older versions of the part 2 regulations going back to 1987, ever intended the outcome that an oral communication made by a part 2 program to a non-part 2 provider, subject to patient consent, would make all subsequent clinical recordkeeping by the non-part 2 provider subject to the requirements of part 2.

The revisions to §§ 2.11 and 2.12 will help to clarify the longstanding balance of interests that part 2 requires, ensuring robust privacy protection for part 2 program treatment records, while also promoting patient safety, reduction of adverse events, and effective coordination of care for persons with SUD. Meanwhile, SAMHSA does acknowledge the importance of making sure that patients understand the contours of their part 2 privacy rights under the revised rule. Again, we are considering opportunities for further guidance and patient and provider education, in connection with the new part 2 rule, as well as in connection with other applicable laws, such as Jessie’s Law, which was enacted as section 7051 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271). Jessie’s Law calls for best practice development and dissemination around the display of an opioid use disorder diagnosis in health care records.

Public Comments

A few commenters said the proposed changes would allow sensitive information about a patient's substance use diagnosis or treatment that is included the general medical record to be shared much more broadly, putting the patient at greater risk of legal prosecution and discrimination. Commenters noted that while HIPAA may still protect the information, it permits much greater access to patient records by law enforcement, insurance companies, entities performing healthcare operations and courts. One commenter said that HIPAA is not sufficiently protective of health condition information that may be highly stigmatized or criminalized. Another said that patients must be able to access care for a SUD without fear of their highly sensitive information being transferred into HIPAA records that offer less protections. A few commenters said the changes will discourage people from seeking help or staying in treatment, including individuals living in areas that are already heavily policed. One commenter said that if any program or activity related to SUD knows that oral communications are no longer considered "records", then actions encompassing the identity, diagnosis, prognosis or treatment of any patient acquired in connection with the performance of that activity will be compromised, which runs counter to SAMHSA's claim of wanting to promote better quality of care for patients.

SAMHSA Response

SAMHSA believes that the revisions to §§ 2.11 and 2.12 offer an appropriate transitional 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. The revised provisions continue to require patient consent, even with oral communications. SAMHSA does not believe that this rule will create the downstream effects of substantially increased discrimination and stigma, nor of substantially decreased patient willingness to enter treatment.

Public Comments

A few commenters said the change to the definition of "records" under § 2.11 would be confusing to patients and providers, including one commenter who found the distinction between receiving an oral disclosure versus a disclosure of paper or electronic records unclear. The commenter noted that all of the part 2 protections cease to apply

once a patient begins sharing information through a patient portal with a non-part 2 provider, since part 2 only applies to part 2 programs.

Several commenters said the proposed change would cause confusion for patients and providers in non-part 2 settings, by requiring different privacy standards for information disclosed orally versus in writing, different layers of protection for the same information, and a process to reconcile written records and oral communications in the receiving provider's system. Another commenter questioned how EHRs will distinguish among information received verbally, information received electronically and scanned, and information received in writing and then rewritten into the chart, which would presumably still enjoy part 2 protection.

SAMHSA Response

As discussed above, although the change to the definition of "records" under § 2.11 applies to oral disclosures made by a part 2 program to a non-part-2 provider, this change will not create a disconnect under part 2 with regard to how other forms of disclosure are treated. Notably, there is no requirement for a recipient, non-part 2 provider to reconcile a received oral disclosure with her own written records. More broadly, the revised §§ 2.11 and 2.12 create no new requirements for the use of EHRs, and no new risks for non-part 2 providers who are already using EHRs in the care of patients with SUDs. Rather, §§ 2.11 and 2.12 together make it clear that non-part 2 providers can create their own patient records, including SUD information, without that activity becoming subject to part 2. Any records previously received from a part 2 program may be segregated, in order to distinguish them from the independent recordkeeping activity of the non-part-2 provider recipient based on her own clinical encounters. And these basic parameters apply equally, regardless of what technology the non-part 2 provider is using to keep his or her own records. SAMHSA does note that using an EHR that supports data tagging and segmentation for privacy and consent management is one path by which a non-part 2 provider could comply with the final rule, particularly with regard to a received electronic record.

In order to address any confusion in the patient and provider communities, SAMHSA is considering opportunities for guidance and educational outreach, in connection with §§ 2.11 and 2.12 specifically, and the new part 2 rule more broadly.

Public Comments

One commenter asked if a patient must give written consent to "verbal" disclosure as well as to "written or electronic" disclosures, and if they could do so by checking distinct boxes.

SAMHSA Response

In general, the part 2 requirements for patient consent to a disclosure of his SUD treatment record by a part 2 program or lawful holder apply regardless of the medium by which any such disclosure is made. Under revisions in this final rule, a patient still must provide written consent in order for a part 2 program to orally share his or her part 2 information with a non-part 2 provider, unless an exception provided for under this Part applies.

Public Comments

One commenter asked for clarification on the difference between the terms, "record," "part 2 record," and "part 2-covered record." The commenter said these terms are not defined. Likewise, another commenter said confusion remains about what constitutes a part 2 record and recommended that SAMHSA engage with stakeholders to inform future guidance that clarifies ambiguity.

SAMHSA Response

SAMHSA appreciates these comments. Although the term "records" is defined under § 2.11, the expressions "part 2 record" and "part 2-covered record" are not defined in the regulation. Broadly speaking, "part 2 record" and "part-2 covered record" both refer to an SUD patient record which is subject to the requirements of part 2, by virtue of originating from a part 2 program. In order to address any confusion in the patient and provider communities, SAMHSA is considering guidance and opportunities for educational outreach, in connection with §§ 2.11 and 2.12 specifically and the new part 2 rule more broadly.

Public Comments

One commenter said it was not clear whether certain facilities, like health centers, would benefit from the changes in §§ 2.11 and 2.12.

SAMHSA Response

SAMHSA appreciates this comment. SAMHSA will monitor the implementation of revised §§ 2.11 and 2.12 in the field, and will consider further guidance on the impact of the revisions to §§ 2.11 and 2.12, including with regard to disclosures by part 2 programs made to non-part 2 health centers.

Public Comments

One commenter appreciated the attempt to bring 42 CFR part 2 into alignment with other privacy rules but said there is still more work to be done to align with HIPAA and across agencies. The commenter said a paper-based workflow point of view is outdated and runs counter to burden-reduction efforts.

SAMHSA Response

SAMHSA appreciates these comments. SAMHSA will consider further revisions to the part 2 regulations in the future, particularly to implement § 3221 of the CARES Act. Several of the related CARES Act provisions will likely have the effect of more strongly aligning part 2 confidentiality standards with the HIPAA privacy rule.

Public Comments

A few commenters said that despite SAMHSA's statement that it does not intend to permit wholesale transcription of the patient's part 2 records into the primary care record, the proposed change may lead to that outcome, especially given the availability of text-to-speech technology applications. One commenter said SAMHSA had provided no parameters on what is permissible beyond the term "clinical purpose," which could result in inappropriate and broad sharing of extensive and potentially damaging information, exposing SUD patients to legal prosecution and discrimination. Another commenter said that if SAMHSA finalizes the proposed amendment to § 2.11, it should include limits on the quantity of information to be transcribed, a clear prohibition on the use of text-to-speech technology for the purposes of this provision, and a requirement that the primary care practitioner counsel the patient on the privacy implications of consenting to such a disclosure, including the ways that HIPAA is less protective of patient privacy than part 2 or applicable state privacy laws.

One commenter applauded SAMHSA's inclusion of language in the preamble addressing the possibility that a non-part 2 provider might transcribe extensively from a part 2 record without having a clinical purpose for doing so and the agency's explicit statement that this is not the intent of the proposal. The commenter urged SAMHSA to incorporate this concept into regulatory text so that non-part 2 providers and other lawful holders are on notice that the intent behind SAMHSA's revised definition of "records" is to facilitate a

treatment discussion between a non-part 2 provider and a patient and not a loophole to circumvent patient privacy and consent. The commenter urged that both §§ 2.11 and 2.12 reference this principle, and asked that § 2.11 specifically note that oral communications from part 2 providers to payers or other third parties are not to be used as the basis of the creation of separate record streams for patients. The commenter also said that SAMHSA should make clear in regulations that its intent behind the revisions to §§ 2.11 and 2.12 is to promote a clinical purpose, such as to allow a treatment note based on a direct clinical encounter with the patient. Short of this clarification, the commenter said SAMHSA should not revise the definition of records to exclude oral communications.

Another commenter suggested that SAMHSA provide sub-regulatory guidance and narrative examples that illustrate acceptable practices regarding the extent of transcription and/or documentation permitted from this change.

SAMHSA Response

As we explained above, the effect of the revision in § 2.11 is to incorporate a very limited exception to the definition of "records," such that a non-part 2 provider who orally receives a protected SUD information 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 for that patient thereafter would become covered by part 2. This provision will not immunize the misconduct of a non-part 2 provider who engages in the wholesale transcription of a received SUD patient record, without her own direct patient encounter and without clinical purpose.

SAMHSA will consider issuing future guidance on acceptable practices regarding the extent of transcription and/or documentation permitted under §§ 2.11 and 2.12 if we find it is necessary.

Public Comments

One commenter said the proposed revisions to the definition of "records" and "applicability" are vague and do not provide any meaningful or clear guidance on what can be added to a medical record without triggering the requirements of 42 CFR part 2. Another commenter asked for clarification as to whether part 2 redisclosure limitations

apply when a treating non-part 2 provider reviews the part 2 program record, transcribes information from that record which has been validly shared pursuant to patient consent, and then inserts it into his or her own treatment record. The commenter asked SAMHSA to confirm that doing so would avoid application of part 2 to the treating provider's record and to broaden the exception to permit portions, summaries, or other extractions from the record to be redisclosed without consent.

SAMHSA Response

As discussed above, the preamble and revisions to §§ 2.11 and 2.12 speak with specificity to the circumstances in which a non-part 2 provider can receive and hold a treatment record from a part 2 program, while nevertheless being able to create her own patient records without fear that these will become covered by part 2. Taken together, the effect of the revisions to §§ 2.11 and 2.12 is to allow a part 2 program to make a disclosure, with the patient's consent, to the recipient non-part 2 provider. In turn, the non-part 2 provider can then carry out her own encounter with the patient, and create her own patient record, which will not fall under the coverage of part 2. Again, segregation of any received SUD record may be used by a non-part 2 provider to ensure that her own created records can be distinguished and will therefore not become subject to part 2.

Consistent with the foregoing explanation, SAMHSA believes that the revised §§ 2.11 and 2.12 strike the appropriate balance in describing how part 2 will apply in these situations.

Public Comments

One commenter asked whether patient SUD treatment information obtained and then recorded by a part 2 program from a non-part 2 provider could be exempt or outside the definition for a part 2 record.

SAMHSA Response

No, that information would still receive part 2 protection. There is nothing in the final rule that modifies the basic definition of "records" under § 2.11, as this applies to a part 2 program. Section 2.11 states, in pertinent part, that "Records means any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient."

C. Applicability (§ 2.12)

SAMHSA is finalizing this section as proposed.

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 proposed to add a new § 2.12(d)(2)(ii), 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 or segmentation 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 believed that this addition will 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 proposed 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 electronic privacy and security tags such as those in an EHR platform leveraging the HL7 Data Segmentation for Privacy (DS4P) standard, 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 the proposed provision 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 provision. 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. Our intent is to expressly permit an avenue of communication, with patient consent, between a part 2 program and non-part 2 provider to facilitate better coordination of care, without automatically triggering application of the rule to the independent records of non-part 2 providers.

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 DS4P standard and recently contributed to the development of the Fast Healthcare Interoperability Resources (FHIR) implementation guide for Consent2Share.⁵ We believe that the existing health IT standards which enable data tagging and data segmentation and which support the SAMHSA Consent2Share tool are important to help 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

⁵ “Consent2Share FHIR Profile Design.docx” can be accessed at <https://gforge.hl7.org/gf/project/cbce/frs/>.

adoption by developers and vendors of EHR systems that meet those standards. The final revisions at § 2.12 do not, however, impose on non-part 2 entities any new requirement for data segmentation as a practice, nor do they establish any new standards or requirements for EHR technology. SAMHSA considered including, in the 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. Segmentation involves technical capabilities and implementation for tagging and consent management, as well as technical specifications to accurately effect disclosure or non-disclosure of data based on federal, state, and local jurisdictions privacy restrictions and patient consent. This requires both technical specifications as well as supporting policies and governance for the treatment of sensitive data that is tagged. The latter is essential for effective segmentation, and segmentation is not achievable solely via adoption of a specific standard, nor is part 2 the only applicable use case for segmentation. For these reasons, we decided not to define segmentation for the purposes of this rulemaking, as such a definition 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 support data tagging and 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 the proposed rule.

In addition to the proposed revision to 42 CFR 2.12(d) above, SAMHSA proposed 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 proposed 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 proposed 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 proposed 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 as lawful holders 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 proposed 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 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 also proposed 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.

The comments we received on the proposed amendments to § 2.12, and our responses, are provided below.

Public Comments

Many commenters supported our proposal to 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, stating that, since the information disclosed to non-part 2 providers will still be governed and protected by HIPAA, the proposal strikes the appropriate balance between allowing for coordination of care and

encouraging patients to seek treatment for a SUD by ensuring patient records remain confidential. Another commenter said SAMHSA’s proposal to allow non-part 2 treating providers to record information about a SUD and its treatment during direct patient encounters without subjecting the information and the record to part 2 would reduce confusion and burden on providers. Several commenters also stated that the policy could help facilitate meaningful communication between part 2 programs and non-part 2 providers. One commenter specifically noted that patients are often surprised when they find out that their records cannot be shared between providers, and this policy may alleviate that concern. Another commenter specifically noted that this proposal is necessary because the schema of DS4P and specifically the Consent to Share tool that SAMHSA proposed in the 2017 Final Rule does not work within a shared electronic health record, but this proposal could.

SAMHSA Response

We thank the commenters for their support.

Public Comments

One commenter, while supporting the proposal, asked for further clarification and guidance on the implementation of the proposed changes so that providers can assure compliance with the regulations.

SAMHSA Response

SAMHSA thanks the commenter for this support. SAMHSA will consider issuing implementation guidance for providers in connection with this rule.

Public Comments

Several commenters opposed our proposal to 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, stating that confidentiality is imperative for building trust, establishing rapport, and creating a therapeutic environment in which individuals are able to explore their mental health needs and substance use history. Some commenters argued that this proposal would deter treatment, infringe the patient-provider relationship, increase stigma, and lead to criminalization. One commenter specifically noted that recent research suggests that healthcare providers perceive patients with documented substance use more negatively than patients with other documented health

conditions, and widely sharing records could lead to negative impacts on care.

SAMHSA Response

SAMHSA believes that the revisions to §§ 2.11 and 2.12 offer an appropriate transitional 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. The revised provisions continue to require patient consent for disclosure of a patient record by a part 2 program for the purpose of treatment, even in the case of oral disclosures. SAMHSA does not believe that these regulations will create downstream effects of substantially increased discrimination and stigma, or of substantially decreased patient willingness to enter into treatment.

Public Comments

One commenter opposed the proposal because of the belief that it made a problematic and stigmatizing assumption that patients have not disclosed their treatment information to their providers. Alternatively, another commenter stated that the proposal would not fix the existing challenges for patient safety, because providers may not be aware of a patient’s history of opioid use disorder when treating the patient for other conditions, even if those other conditions are related to the SUD.

SAMHSA Response

SAMHSA believes that the revisions to §§ 2.11 and 2.12 will help to improve the coordination of care between part 2 programs and non-part 2 providers, as well as by non-part 2 providers who receive an SUD patient record disclosed to them by a part 2 program. Rather than making a stigmatizing assumption that patients have not disclosed their SUD treatment information to their [non-part 2] providers, the revisions to §§ 2.11 and 2.12 are intended to facilitate both patients and providers in carrying out exactly those disclosures. Although SAMHSA anticipates that these revisions will help to enhance quality of care efforts and to improve patient safety, it is unlikely that any single policy reform under part 2 will fully resolve the adverse events and safety problems associated with the opioid epidemic. SAMHSA will continue to consider a range of other policies and interventions to address the public health impact of the opioid epidemic in the future.

Public Comments

Several commenters asked for clarification regarding the recording of part 2 information by a non-part 2 provider in a patient's record. One commenter stated that the proposal was too vague and did not provide any meaningful or clear guidance on what can be added to a medical record without triggering the requirements of 42 CFR part 2. Another commenter asked if the proposal would result in the entire record being enveloped in part 2. A few commenters asked us to clarify whether a non-part 2 provider's act of copying and pasting relevant information from a patient's part 2 program record into a non-part 2 record would constitute the "recording" of SUD information and thus preclude the application of part 2 to the non-part 2 record. Commenters requested detailed guidance to ensure part 2 programs and treating providers are aware of the permissible means to transfer SUD information. One commenter specifically requested guidance on the nature and extent of data that can arise from treatment discussions informed by part 2 data or clinically relevant transcription and whether data segmentation/tagging of such a non-part 2 record is required. The commenter also urged more evaluation and real-world implementation testing with respect to the implementation, standards, and technology issues associated with both clarifications.

SAMHSA Response

As discussed above, we believe both the preamble and revisions to §§ 2.11 and 2.12 speak with specificity to the circumstances in which a non-part-2 provider can receive and hold a treatment record from a part 2 program, while nevertheless being able to create her own subsequent patient records without fear that these will become covered by part 2. Notably, there is nothing in the final rule that would cause an entire record to be "enveloped in part 2," any more so than is the case now. Again, the effect of the revisions to §§ 2.11 and 2.12 is to allow the part 2 program to make a disclosure, with the patient's consent, to the recipient non-part 2 provider. In turn, the non-part 2 provider can then carry out her own encounter with the patient, and create her own patient record, which will not fall under the coverage of part 2. Segregation of any received SUD record may be used by a non-part 2 provider to ensure that her own created records can be distinguished, and will therefore not become subject to part 2.

Taken together, SAMHSA believes that the revised §§ 2.11 and 2.12 strike the appropriate balance in describing how part 2 will apply in these situations. SAMHSA is considering future guidance to clarify the requirements of §§ 2.11 and 2.12 for providers, and SAMHSA will continue to collaborate with other federal agencies in regard to technology implementation and standard-setting that touches on part 2 records.

Public Comments

One commenter stated opposition to any limitations on how, when or how much SUD information the non-part 2 provider can document within its own record, even when that information is transcribed from a received record from a part 2 program. This commenter stated that the preamble implies that, in order for part 2 not to apply, the non-part 2 provider needs to document the SUD information as part of a direct clinical patient encounter and upon reviewing it with the patient first, as opposed to directly copying from a record received from a part 2 program. The commenter stated that for appropriate care, non-part 2 providers should be able to document SUD information for safe patient care without the information becoming subject to 42 CFR part 2, regardless of how a part 2 program originally provides the information, or whether information is independently discussed with the patient during a visit.

SAMHSA Response

SAMHSA believes that the revisions to §§ 2.11 and 2.12 offer 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. As discussed below, SAMHSA is also modifying the regulatory text in § 2.33(b), to add disclosures for the purpose of care coordination and case management to the list of permitted activities. Other forms of communication between lawful holders of part 2 records are also permitted under the part 2 regulations with patient consent, consistent with the enabling statute. The revisions to §§ 2.11 and 2.12 reflect a balance of interests between ensuring robust privacy protection for part 2 program treatment records, while also pursuing patient safety, reduction of adverse events, and better coordination of care for persons with SUD. SAMHSA will continue to consider opportunities for further re-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 the part 2 enabling statute and consistent with § 3221 of the CARES Act.

Public Comments

One commenter asked if the process of using the capabilities of certified electronic health record technology (CEHRT) to electronically "copy" a medication item, a problem or a medication allergy from the received part 2 document as an external list to the internal list maintained by the non-part 2 provider's CEHRT is considered "transcription." This commenter asked that we include an example discussing a form of transcription that is permitted that does not violate the handling of a part 2 record received by a non-part 2 provider.

Likewise, another commenter specifically recommended that we revise the proposed regulations to allow health systems/providers using an integrated EHR to include the following in the patient's EHR without the patient's consent: Part 2 SUD in the integrated common problem list; Part 2 SUD treatment/post treatment medications on the integrated common medications list; medication allergies found during Part 2 SUD treatment/post treatment encounters on the integrated common medication allergy list; and an exception to obtaining a patient's consent to share this information for health systems/providers who use an integrated EHR.

SAMHSA Response

Currently, a part 2 program may make a disclosure with the patient's consent to a non-part 2 provider. Taken together, the effect of the revisions to §§ 2.11 and 2.12 is to clarify that the non-part 2 provider can then discuss that information in her own encounter with the patient, and create her own patient record that includes SUD information which will not be subject to part 2. The recipient non-part 2 provider is permitted but not required to segregate the received part 2 record (in whatever medium is relevant), as a way to ensure that her own subsequent record-keeping activity can be distinguished. These general principles continue to apply, regardless of whether the recipient non-part 2 provider is using a CEHRT [certified electronic health record technology] or whether the recipient non-part 2 provider and the part 2 program exchange their communications through a common, integrated EHR platform.

SAMHSA believes that revised §§ 2.11 and 2.12 strike the right balance of interests between ensuring robust privacy protection for part 2 program

treatment records, while also promoting patient safety, reduction of adverse events, and better coordination of care for persons with SUD. SAMHSA will continue to consider future guidance and refinement to the part 2 rules, and will continue to work with ONC to support and implement health IT policies consistent with the part 2 rules.

Public Comments

Many commenters asked for further clarification from SAMHSA in determining which records and providers are subject to part 2 requirements. Commenters specifically asked for definitions as to what “holding oneself out as providing” entails. Other commenters noted that, in the current healthcare environment and its emphasis on integrated care, providers are likely to apply the Part 2 requirements to more treatment settings and providers than required, creating excess compliance burden. Some commenters also noted that it is hard to imagine a scenario in which part 2 would prevent a specialist for any other chronic disease from supporting a treatment team without subjecting the entire team to unwieldy regulations. Commenters also stated that further clarification of the definition of a part 2 program could help patients choose which type of providers—and, consequently, confidentiality protections—they should seek.

One commenter recommended that SAMHSA clarify that Medication-Assisted Treatment (MAT) services and their associated workflows provided as part of a general medical facility do not meet the definition of a part 2 program, as long as the providers rendering the MAT services do not do so as their primary function within the facility. This commenter also recommended that SAMHSA clarify that any education or outreach (including posting notices, advertising and informing patients) about the availability of MAT services at a general medical facility, including Indian Health Service (IHS) and tribal facilities, would not change its status as a non-part 2 provider.

SAMHSA Response

SAMHSA appreciates these comments. Although outside the scope of the current rulemaking, SAMHSA will consider issuing guidance in the future to further clarify when a general medical facility is subject to the part 2 regulations.

Public Comments

A few commenters asked us to provide further guidance to clarify how health plans may similarly

communicate with non-part 2 providers without subjecting their own records to part 2. Commenters asked if the proposed change applies to other lawful holders, specifically health plans.

SAMHSA Response

The revisions in § 2.12 establish that SUD treatment records created by a non-part 2 provider will not be covered by part 2, unless any SUD record previously received from a part 2 program is incorporated into such records. Under § 2.12, segregation of the received record can be used by non-part 2 providers to ensure that their own created patient records can be distinguished from the received record, and thus will not become covered by part 2.

The revisions in § 2.12 do not address the direct disclosure made by a health plan to a non-part 2 provider. In general, the broader part 2 framework concerning disclosures made by health plans as “lawful holders” continue to apply. SAMHSA will consider issuing future guidance to clarify the application of part 2 to disclosures of SUD records by health plans.

Public Comments

One commenter suggested that rather than modifying § 2.12 in order to facilitate disclosures by part 2 programs to non-part 2 providers in support of care coordination, it would instead be more effective under § 2.33 to add care coordination to the list of payment and operations activities for which a disclosure may be made with patient consent.

SAMHSA Response

SAMHSA believes that the current revisions to § 2.12 create an appropriate and limited pathway for part 2 programs to disclose SUD records to non-part 2 providers, and then to allow non-part 2 providers to create their own treatment records based on subsequent clinical encounters with their patients. However, as we explain below under § 2.33, SAMHSA has decided to modify the regulatory text in § 2.33(b), by adding disclosures for the purpose of care coordination and case management to the list of permitted activities under that section.

Public Comments

One commenter specifically recommended that SAMHSA clarify that systems that permit secure communication between patients, their permitted designates and non-part 2 caregivers may be used by part 2 caregivers that are employed by the same healthcare organization, or that

use the same implementation of the secure communications system. This commenter also asked us to exempt communications between part 2 providers and non-part 2 healthcare providers that are actively engaged in the care of the same patient, but are not employed by the same healthcare organization. This commenter also asked that we specify that part 2 providers performing hospital consultation work may communicate with non-part 2 providers within the same organization without generating a part 2 covered record.

SAMHSA Response

Communications between patients, part 2 programs, and non-part 2 providers through patient portals and integrated EHR platforms can present an array of challenges and scenarios for patient consent under part 2. The current rulemaking does not attempt to address or resolve all such situations, nor does it change the status quo of how part 2 applies in many such situations.

SAMHSA will consider future guidance with regard to the application of part 2 to integrated EHR platforms, and particularly within integrated healthcare systems that include both part 2 programs and non-part 2 providers within the same system.

Public Comments

One commenter noted that SAMHSA did not make any proposals related to “Jessie’s Law.” The commenter explained that Jessie’s Law requires HHS to develop best practices for prominently displaying information relating to a patient’s history of substance use in his or her treatment records when the patient makes a request for such disclosure.

SAMHSA Response

We will continue to work within HHS to ensure that we are complying with any applicable legal requirements stemming from Jessie’s Law.

Public Comments

Several commenters noted support for our description of segregating records, specifically appreciating that we did not impose any new requirement for data segmentation as a practice or establish new standards for EHR technology. Commenters stated that this segregation policy should be flexible to allow providers with different operational capabilities to implement the policy in the least burdensome way and to offer an opportunity for the health IT industry to continue to work with stakeholders in the development of standards to meet patient privacy

expectations. One commenter stated the proposal would not incur significant additional burden on vendors because segmenting part 2 data has become an industry norm with the implementation of the Data Segmentation for Privacy standard, as well as the recent FHIR implementation guide for Consent2Share.

SAMHSA Response

We thank the commenters for their support.

Public Comments

A few commenters expressed clinical concerns with segmenting records, stating that to do so erodes the reliability of those records to support the delivery of safe care and may discourage the use of EHRs for specific types of SUD information. One commenter noted that this concern is especially important because FDA medical device guidance requires visibility into how IT systems arrive at their recommendations, which may not be possible in a world of segmented data. One commenter cautioned us, for these reasons, to only use data segmentation and separation in a limited way.

SAMHSA Response

The revisions in § 2.12 do not impose any requirements for non-part 2 providers to segment their electronic health records. Neither do the current revisions in § 2.12 impose any standards for segmenting electronic health records more generally. We believe it is important that providers include clinically relevant information within their records, while still respecting confidentiality requirements.

SAMHSA is sensitive to concerns about segmentation standards for EHRs. However, SAMHSA is not introducing new segmentation requirements or standards under this rule-making.

Public Comments

Some commenters supported the policy of segregating records under § 2.12, but said it is not a practical or best solution to promote the effective handling of SUD information to permit treatment and care coordination, noting that that the proposed changes still do not allow the exchange of information for these purposes without the written consent of the patient. These commenters argued that the policy would be burdensome and costly, and, because of the multitude of different operational standards and capabilities, part 2 programs will find themselves in an economically burdensome and legally questionable position as legal

holders of information disclosed to them by patients seeking care. A few of these commenters also noted, however, that these burdens could not be overcome without statutory changes.

SAMHSA Response

We appreciate these comments. The revised § 2.12 does continue to require patient consent for the disclosure of a patient SUD record by a part 2 program to a non-part 2 provider. The revised § 2.12 reflects a balance of interests between ensuring robust privacy protection for part 2 program treatment records, while also promoting patient safety, reducing adverse events, and facilitating better coordination of care for persons with SUD.

SAMHSA does not believe that the revised § 2.12 will place part 2 programs under any greater operational or legal burden than they currently face, with regard to making disclosures to non-part 2 providers. Meanwhile, it would go considerably beyond the current rulemaking, and the current authorizing statute, to permit the disclosure of a patient record by a part 2 program to a non-part 2 provider, without the consent of the patient, except as otherwise permitted under Part 2.

Public Comments

A few commenters asked us to clarify the scenario in which one entity has Part 2 and non-Part 2 providers utilizing the same EHR that automatically populates diagnosis and prescription information. Commenters requested SAMHSA expand its proposal to clarify that if a general medical facility includes both Part 2 and non-Part 2 providers, then basic information that prepopulates, such as diagnosis and prescription information, is not subject to Part 2 requirements. Commenters further explained that some providers are unable to segregate records with any degree of confidence in their current workflows, and noted that many health systems either use separate EHRs or consider all providers in the system Part 2 providers due to burden and cost, which makes the referral of SUD and non-SUD patients and their health records more complicated. Other commenters similarly noted that they must treat all possible Part 2 information as if it were subject to the rule, and that requiring segmentation of part 2-protected patient records to prevent unauthorized redisclosure may be strictly interpreted by the non-part 2 recipients, causing the information to be inaccessible for care coordination or other purposes beneficial for the patient.

SAMHSA Response

Taken together, the effect of the revisions to §§ 2.11 and 2.12 is to allow the part 2 program to make a disclosure, with the patient's consent, to the recipient non-part 2 provider. In turn, the non-part 2 provider can then carry out her own encounter with the patient, and create her own patient record, which will not fall under the coverage of part 2. The recipient non-part 2 provider is permitted, but not required, to segregate the received part 2 record (in whatever medium is relevant), as a way to ensure that her own subsequent record-keeping activity can be distinguished. These general principles continue to apply, regardless of whether the recipient non-part 2 provider and the part 2 program exchange their communications through a shared, integrated EHR platform.

SAMHSA believes that revised §§ 2.11 and 2.12 strike the right balance of interests between ensuring robust privacy protection for part 2 program treatment records, while also promoting patient safety, reduction of adverse events, and better coordination of care for persons with SUD. SAMHSA will consider future guidance with regard to the application of part 2 to integrated EHR platforms, and particularly within integrated healthcare systems that include both part 2 programs and non-part 2 providers within the same system.

Public Comments

One commenter specifically noted concerns for IHS or tribal facilities still using the full Resource and Patient Management System (RPMS) EHR system. This commenter stated that, while non-part 2 IHS or tribal facilities could segregate a paper record fairly easily, the RPMS system does not allow for the segregation of electronic records. For this reason, the commenter recommended that IHS and tribal facilities using RPMS be exempted as to compliance with part 2 until IHS modernizes its EHR system. This commenter also asked that SAMHSA conduct tribal consultation to negotiate with tribes on part 2 compliance as to IHS and tribal facilities.

SAMHSA Response

It is beyond the scope of the current rulemaking for SAMHSA to address specific operational challenges for IHS or tribal facilities associated with part 2. SAMHSA notes, however, that there is no new requirement under § 2.12 for a non-part 2 provider to segregate any SUD records received from a part 2 program. There is also no requirement

under the revised § 2.12 for record-keeping practice at IHS or tribal facilities to change. Segregating a received part 2 record under § 2.12 is entirely at the option of the recipient provider.

Regardless, SAMHSA will consider conducting future tribal consultations and outreach around the revised part 2 rule, as an input to future guidance on implementation and compliance.

Public Comments

Several commenters stated what is meant by requiring the records to be “segregated” or “segmented” is unclear and unrealistic, and may mean creating an entirely separate EHR or resorting to paper medical records. One commenter suggested that SAMHSA should propose alternate solutions to segmentation by non-part 2 providers of records received from part 2 programs, which could ease provider burden. Commenters specifically noted concerns with technological barriers to segmenting non-Part 2 covered patient data, because current EHR technology does not allow for a provider to share just the non-Part 2 covered patient information with other providers, and asked SAMHSA to offer guidance. Commenters noted that, currently, there are no federal requirements for EHRs to include DS4P standards, and that, absent a requirement imposed on electronic medical record vendors to adopt DS4P and requirements for receiving providers to have a consent management system, this situation is unlikely to improve. Commenters also questioned whether it is feasible to require DS4P standards in all EHRs and urged SAMHSA to pursue additional testing of the DS4P standards and to work with developers and ONC on a solution. One commenter said that expecting programs to adopt compliant medical records could be expensive, disruptive to patient care, and problematic for many programs. As an alternative, this commenter suggested establishing minimum requirements for all EHRs through the appropriate EHR regulations.

SAMHSA Response

There is no requirement under revised § 2.12 for a non-part 2 provider to segregate or segment an SUD treatment record received from a part 2 program. It is beyond the scope of the current rulemaking to address a wide range of technical concerns about support for segmentation under specific EHR technologies; or concerns about the development or refinement of future DS4P standards; or concerns about the cost or burden to providers of adopting

EHR systems in the future. None of these concerns detracts from the central premise of § 2.12, which is to establish that a patient record created by a non-part 2 provider will not become subject to part 2, simply because SUD information may be included within that record.

Nevertheless, SAMHSA remains broadly sensitive to concerns about segmentation, DS4P standards, and EHRs. SAMHSA will continue to collaborate with ONC and CMS on efforts that relate more directly to interoperability and standard-setting for EHRs.

Public Comments

Although some commenters appreciated that SAMHSA did not prescriptively state a requirement for use of the electronic data segmentation approaches, they similarly noted that DS4P and FHIR standards are still unsettled topics. Commenters explained that, while policies have been adopted and are being further proposed to “tag” sensitive health information in various ways, no progress has been made to provide support to identification of “what” is sensitive in a way that is semantically interoperable or at a meaningful level of data granularity. To make data segmentation a reality that is not burdensome, these commenters stated that many stakeholders must decide how sensitive health information can be “tagged.” Even with this consensus, some commenters expressed concern that tags are not persistent through transfer because DS4P does not detail how recipient systems should handle tagged data, and the scenarios under which it is appropriate to use/disclose data tagged as sensitive.

Commenters noted that these technical aspects will require a significant investment in time and resources to ensure the alignment of technical infrastructure and policy approaches for both EHRs and health information exchanges, requiring policy responses as well as the upgrade and maintenance of data dictionaries and technology components. Therefore, commenters urged SAMHSA to continue working with ONC on these issues. One commenter strongly urged SAMHSA to demonstrate commitment to greater interoperability and privacy protections by prioritizing data segmentation in development, testing, and policymaking, specifically noting the need for data segmentation to be made accessible and affordable to physicians.

SAMHSA Response

SAMHSA acknowledges that many technical issues and standards with regard to data segmentation and tagging practices remain unresolved, and are continuing to evolve rapidly. SAMHSA will monitor the field and continue to work with ONC on these issues, and will likewise collaborate with ONC and CMS on efforts that relate more directly to interoperability and standard-setting for EHRs. Regardless, SAMHSA continues to believe that EHRs that support tagging and segmentation offer one approach for implementing part 2 compliant clinical workflows.

Public Comments

A few commenters asked us to clarify if “segregation” or “holding apart” applies to claims data, which may hold information about a patient’s diagnosis and treatment. One commenter asked that we work with ONC to clarify how treatment of SUD data by non-Part 2 providers will work under information blocking and TEFCAs and administrative transaction policies.

SAMHSA Response

Under § 2.12, it is contemplated that a part 2 program may disclose a treatment record to a non-part 2 provider with the consent of the patient, in support of better coordination of care. In turn, the non-part 2 provider may then carry out her own clinical encounter with the patient, and create her own patient record that includes SUD information, without that record being subject to part 2. The non-part 2 provider may segregate any record previously received from the part 2 program as a way to distinguish this from her own clinical records. Note that all of the foregoing assumes an initial disclosure of a clinical record or information for treatment purposes, rather than a disclosure of claims data, by the part 2 program to the non-part 2 provider. A disclosure involving a claim would typically involve a health plan as a recipient, which is beyond the scope of the current revision of § 2.12 to address.

SAMHSA will continue to collaborate within the department on any potential future guidance as may involve health IT.

Public Comments

One commenter noted support of our proposal to clarify the language of § 2.12 from the use of “any information” to “any records,” and agrees that it better illustrates the intent SAMHSA describes in the preamble.

SAMHSA Response

We thank the commenter for its support.

Public Comments

One commenter asked for clarification on whether there is a distinction (or conversely, an ambiguity) between what constitutes the legally recognized medical record, versus shared information that is structured and record-like. In other words, at what threshold of structure and formality of conveyance does “information” become “record?”

SAMHSA Response

SAMHSA does not draw any distinction between “records” as defined under § 2.11, versus “shared information that is structured and record-like.” Per the regulatory text of § 2.11, a “record” is defined as “any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient.”

D. Consent Requirements (§ 2.31)

SAMHSA is finalizing this section as proposed, and adding further guidance concerning the application of § 2.31 to disclosures for the coordination of care, as outlined below.

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 SUDs would like part 2 programs to disclose their 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.

We also understand that the requirement to include an individual’s name could make it more burdensome for part 2 programs or lawful holders to facilitate a patient’s specific consent to share their information with a contractor or subcontractor that performs care coordination or case management activities on behalf of the program or lawful holder. It is not SAMHSA’s intent to limit patients’ ability to consent to the disclosure of their own information or create barriers to care coordination. We wish, rather, to empower patients to consent to the release and use of their health

information in whatever way they choose, consistent with statutory and regulatory protections designed to ensure the integrity of the consent process.

Therefore, in this final rule, SAMHSA is amending the current regulations to clarify when patients may consent to disclosures of part 2 information to organizations without a treating provider relationship. In particular, SAMHSA has amended § 2.31(a)(4)(i), which previously required a written consent to include the names of individual(s) to whom a disclosure is to be made. The amended section inserts 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. In addition, in response to the many comments requesting that SAMHSA provide more flexibility throughout the rule to facilitate care coordination and case management, the change at § 42 CFR 2.31(a)(4)(i) will also make it easier for patients to consent to the disclosure of their information for the purposes of care coordination and case management, including to contracted organizations of lawful holders, by naming such organizations on the consent form.

SAMHSA has removed old § 2.31(a)(4)(ii) and (iii)(A), and redesignated old § 2.31(a)(4)(iii)(B) as § 2.31(a)(4)(ii) in the final rule. SAMHSA has also amended 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 section establishes 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. We have also made conforming amendments to §§ 2.12(d)(2)(a) and 2.13(d). The revised language of 2.31(a)(4) does continue to permit patient consent to disclosures to third-party payers based on naming the recipient entity, without specifying an individual recipient at that entity.

The comments we received on this proposal and our responses are provided below.

Public Comments

Many commenters supported our proposal to allow patients to consent to disclosure to entities without a treating provider relationship without naming the specific individual receiving the information. These commenters stated that this proposal would break down barriers for patients and remove delays in seeking and receiving often life-saving services or benefits from entities, allowing integrated information exchange between all necessary services, including collaborative non-treatment services related to substance use. Commenters believed that this proposal would empower patients to determine whether it is in their interest to share their own protected SUD information with health and social service entities, putting “patients over paperwork.” Commenters also noted that this proposed change would align with the modern innovations of complex, fluid teams that meet individual patient needs and “whole person” care models, many of which may address underlying social determinants that can affect a patient’s health status. Commenters also noted the proposal would significantly enhance efforts at interoperability and getting information where and when it is needed at the point of care. Finally, commenters applauded this change because it is more closely aligned with HIPAA standards.

SAMHSA Response

We thank the commenters for their support.

Public Comments

Several commenters opposed this proposal, fearing that information would be given to interconnected health care systems, unknown future entities, and vendors with one general consent and signature. One commenter asked that the consent continue to include the specific information to be shared, with whom specifically, and the time constraints of the release of information. A few commenters stated that the proposal raised trust, privacy, and

confidentiality concerns and would deter treatment. One commenter asked that this consent be an “option” rather than “preferred.”

SAMHSA Response

As noted above, SAMHSA has learned that some patients with SUDs may want part 2 programs to disclose protected information to entities for reasons including eligibility determinations and seeking nonmedical services or benefits from governmental and non-governmental entities (e.g., social security benefits, local sober living or halfway house programs). However, the old rule precluded patients from designating an entity’s name by itself on the consent form, unless the entity was a third-party payer. To alleviate frustration and delays in applying for and receiving services and benefits, SAMHSA amended the regulations to clarify that patients may consent to disclosures of part 2 information to organizations without a treating provider relationship. We note that § 2.31(a)(5) requires the consent form to include the purpose of the disclosure, which must be limited to that information which is necessary to carry out the stated purpose. Under § 2.31(a)(7), the consent form must include the date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is provided. We believe that these safeguards will alleviate any concerns that the consent may be too broad, while appropriately allowing the patient to choose to whom their records are disclosed.

Public Comments

Many commenters asked us to further expand the proposal to allow broader consent. A few commenters recommended that we make additional revisions which would permit generalized consents, authorizing both disclosures and re-disclosures of Part 2 records for treatment, payment, and health care operations (TPO) purposes among HIPAA “covered entities,” Part 2 programs, and HIPAA “business associates” to receive their full medical records, noting this global consent would result in better care coordination and avoid delays. Another commenter recommended adding regulatory language to specify that patients may consent to permit both their Part 2 facility and health information exchange networks of their choosing to disclose their health information to past, present, and future treating providers. Another

commenter requested that we allow consent for information to be disclosed to categories or types of organizations. Similarly, a few commenters requested that we clarify that organizations like accountable care organizations and health homes can be considered to have a “treating provider relationship” with a patient. Likewise, a few commenters asked us to clarify whether the proposed changes apply to entities that receive information from Part 2 providers for non-treatment purposes such as health plans, business associates, healthcare clearinghouses, and third-party payers. These commenters claimed that there is little to no legal distinction between broadening the To Whom requirement for non-treatment and treatment purposes under Part 2, and that broadening in this way could help to streamline Part 2 and HIPAA.

SAMHSA Response

As noted above, under § 2.31, patients control to whom and for what purposes they consent to disclosure of information. Under this proposal, SAMHSA is amending the regulations to clarify that patients may consent to disclosures of part 2 information to organizations without a treating provider relationship. We believe that this policy appropriately balances patients’ empowerment with confidentiality concerns.

However, the change we are making will make it easier for patients to consent to share their records for the purposes of care coordination and case management. Patients may consent to share their information with a contractor or subcontractor that performs care coordination or case management on behalf of a part 2 program or lawful holder, if the consent form specifies the contracted organization name in the “to whom” section, describes the specific types of activities to be undertaken in the “purpose” section; and meets all other required elements outlined in § 2.31. Similarly, a patient may consent to share their records for the purpose of care coordination with his or her treating provider organization or health insurer, if the provider organization or health plan is named in the “to whom” section and the specific types of care coordination or case management activities are described in the purpose section of the consent form.

SAMHSA will consider making further revisions to the consent requirements under § 2.31 in the future, particularly as needed to implement § 3221 of the CARES Act.

Public Comments

One commenter requested clarification regarding the proposed changes to § 2.31 (a)(4)(ii)(B), specifically asking about a scenario in which a part 2 program includes a statement on a consent form to share part 2 information with a PDMP, and must, upon request, provide the patient with a list of entities to which their information has been disclosed pursuant to the general designation in § 2.13(d). The commenter inquired about the level of specificity that is required for the “list of entities.” This commenter noted that a state may only have the ability to disclose that a patient’s information was accessed by another state’s PDMP, but may not have access to the records for individual end-users in that state’s PDMP.

SAMHSA Response

Under § 2.36, disclosures to PDMPs will be accomplished by direct consent and not using a general designation to which the List of Disclosures requirement in § 2.13(d) applies. As a result, a patient would not be able to request a list of entities under § 2.13(d) to which the PDMP made disclosures.

Public Comments

One commenter argued that there should be an option for a “general designation” that encompasses all providers within an organization, not just those who already have a treatment relationship with the patient. This commenter asked that we add the following language to the regulation: “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 or who has in place a written contract or comparable legal instrument with the individual or entity that requires the participant(s) to be fully bound by the provisions of Part 2 upon receipt of patient identifying information.”

SAMHSA Response

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.

Public Comments

A few commenters supported our proposal, but asked us to provide additional examples and definitions of “entity” in the final rule. Commenters noted that this clarification would help providers comply with the provision. One commenter asked that we clarify the applicability of § 2.31(a)(4)(i) to third-party administrators and/or representatives that operate on behalf of a governmental and/or nongovernmental entity. The commenter also asked us to clarify under the proposed rule the applicability of § 2.31(a)(4)(i) in instances in which the requirements of § 2.15(a)(1) have been met and a patient’s guardian or personal representative authorized under state law may act on behalf of the patient. A few commenters asked us to carefully define “entity” to specify an individual or entity that has a direct treating provider or clinical relationship with the patient.

SAMHSA Response

SAMHSA is amending § 2.31 to enable patients to broadly consent to disclose their records to any entity of their choosing, without naming an individual recipient within such entity. A patient may choose to disclose their records to an entity with which they do not have a treating provider relationship, except in situations where a general designation is used to disclose information to entities that facilitate the exchange of health information or to research institutions. In that case, a general designation of an individual or entity participant(s) or class of participants must be limited to a participant(s) with a treating provider relationship with the patient whose information is being disclosed. Given our desire to ensure patients may consent to any entity or its representatives as they so choose, SAMHSA does not believe that further defining the term “entity” is necessary. Section 2.15(a) states that in the case where a patient has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage their own affairs, any consent that is required under the regulations in this part may be given by the guardian or other individual authorized under state law to act in the patient’s behalf.

Public Comments

A few commenters asked us to include anti-discrimination protections in the regulations that forbid the use of any information disclosed for the purposes of limiting access to health, life, or disability insurance coverage; limiting access to protections under the ADA; limiting access to health care; criminal or civil investigation or prosecution; sharing information with the patient’s employer; sharing information with child welfare agencies or family courts; or limiting or denying the patient’s rights or benefits in any way.

SAMHSA Response

As we have previously indicated, promulgating rules that address discriminatory action is outside the scope of SAMHSA’s current legal authority (see 83 FR 248). However, we refer the commenter to § 2.13(a), which states that patient records subject to the Part 2 regulations may be disclosed or used only as permitted by the regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority. Further, §§ 2.64 and 2.65 describe required procedures and criteria for orders authorizing disclosures for criminal investigations of patients and for non-criminal purposes (such as a civil action), which provide safeguards for patients. Finally, we note that § 3221(g) of the CARES Act does include antidiscrimination language, and we anticipate implementing that provision in future rulemaking.

Public Comments

One commenter requested clarification as to how the proposal would apply to a medical entity such as a clinic. The commenter asked if all providers dealing with the patient in a clinic would have access to the disclosed information. The commenter stated that it is their understanding that some treatment records can be marked as confidential in certain electronic health records, but that medications and diagnoses typically are not.

SAMHSA Response

Although SAMHSA has amended the current regulations to clarify that a patient may consent to the disclosure of part 2 information to an entity without naming a specific individual as the recipient, current rules already allow consent to an entity with a treating provider relationship, and this consent flows to entity staff with a need to access the Part 2-covered information.

We note that § 2.31(a)(5) of the regulations continues to require the consent form to include the purpose of the disclosure. The disclosure of patient identifying information must be limited to that information which is necessary to carry out the stated purpose. Thus, a clinic receiving the disclosed information may only share the patient's information in order to meet the purpose of the disclosure as described on the consent form.

Public Comments

One commenter recommended that a tribally operated or American Indian part 2 program be authorized to share a patient's SUD treatment information with IHS, tribal, or urban Indian health primary care providers for treatment purposes without patient consent, stating that this change is needed to facilitate care within the Indian health system.

SAMHSA Response

We appreciate the comment and concern for ensuring patients within the Indian Health Service receive effective care. SAMHSA does not have the authority to exempt patients within the IHS from the part 2 consent requirements. However, we note that the changes we are finalizing in this final rule to promote care coordination between part 2 programs and primary care doctors would similarly apply to IHS providers and patients.

Public Comments

One commenter asked us to develop template consent forms that meet the requirements of the final rules for ease and convenience of patients and providers.

SAMHSA Response

We thank the commenter for the suggestion and will consider issuing guidance related to the consent form requirements in the future.

Public Comments

A few commenters asked that we allow for an "opt-out" consent process similar to that under HIPAA, in which patient information would be permitted to be used and disclosed for treatment, payment, and health care operations unless the patient opts-out.

SAMHSA Response

The authorizing statute for the part 2 rules expressly requires written consent for most uses and disclosures of SUD patient records. We believe that this policy appropriately balances patients' empowerment with confidentiality concerns. We further note, however,

that § 3221 of the CARES Act contemplates modifying the parameters for consent to the disclosure of a patient record for the purpose of treatment, payment and health care operations. We anticipate making further revisions to part 2 in the future, in order to implement the relevant provisions of the CARES Act.

Public Comments

One commenter encouraged us to expand the list of safe harbors for those acting in good faith who are trying to help an individual obtain housing, health care, or other necessary services. The commenter also asked us to align with the HHS Office for Civil Rights (OCR) on future regulations and guidance specifically discussing these scenarios and the ability to share health information for critical individual needs.

SAMHSA Response

We thank the commenter for the suggestions and will consider them in the future.

Public Comment

One commenter requested clarification on how patient confidentiality will be assured under this proposal.

SAMHSA Response

As noted above, records are only disclosed at the patient's request and after consent under this section; therefore, the patient remains in control of his/her records and with whom and for what purposes these records are shared. Records disclosed under this section will retain their status as protected part 2 records in the hands of downstream recipients. We refer the commenter to § 2.32, which describes the notice that must be provided to recipients of part 2 records disclosed under § 2.31. The notice prohibits redisclosure of the records unless expressly permitted by the written consent of the individual whose information is being disclosed or, otherwise permitted by 42 CFR part 2.

Public Comments

One commenter stated that the rule change needed to be clarified across the regulation to ensure that individuals do not need to be listed to consent to an entity.

SAMHSA Response

SAMHSA believes that clarifying this change in the regulatory text of § 2.31 is sufficient to ensure that individuals do not need to be listed when a patient

consents to sharing his or her records with an entity.

Public Comments

One commenter, although supporting our proposal, noted the importance of the safeguards inherent in the general designation that allow the individual to request a list of entities to which their information has been disclosed.

SAMHSA Response

We appreciate feedback regarding the importance of safeguards that allow an individual to request a list of entities to which their information has been disclosed under the general designation option.

Public Comments

A few commenters requested that we allow individuals to consent to disclosure to entities without listing an individual as the recipient, in instances where information is disclosed to entities that facilitate the exchange of health information or research institutions. These commenters stated that patients are not aware of the information sharing happening at the provider level by Health Information Networks (HINs) and HIEs, most of which is done to coordinate care and benefit a patient's care. Without this change, commenters said that Part 2 information sharing that is happening at the HIN and HIE level could be halted, and burden to providers may increase. Commenters also argued that this change is also not legally different than adopting the same position with respect to treatment purposes and this change would align with the CMS and ONC interoperability goals.

SAMHSA Response

Newly finalized language in § 2.31(a)(4)(ii) continues to allow patients to use a general designation in consenting to disclose their records to organizations that facilitate the exchange of health information. Specifically, if a recipient entity facilitates the exchange of health information or is a research institution, a written consent must include the name(s) of the entity and either the name of the individual or entity participants, 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 (e.g., "my treating providers").

Public Comments

One commenter noted that SAMHSA did not provide a definition in the

proposed rule on what constitutes an HIE, and asked us to define what types of organizations qualify as HIEs.

SAMHSA Response

On May 1, 2020, ONC published its final rule on interoperability under the 21st Century Cures Act (85 FR 25642). As a part of the final interoperability rule, ONC did provide a definition for what constitutes an HIE (to be codified at 45 CFR 171.102). SAMHSA is hereby incorporating that definition by reference, for the purpose of this rule.

Public Comments

One commenter noted the tension between the functionality of an HIE and protecting patient privacy. This commenter encouraged us to carefully explore the relationship between part 2 data and HIEs in future guidance, in order to identify solutions that can allow for rapid data transfer while protecting patient privacy.

SAMHSA Response

We thank the commenter for this suggestion and will consider issuing additional guidance related to HIEs in the future. SAMHSA will also consider other educational activities, such as trainings and webinars, should SAMHSA determine the need during implementation of the final rule.

Public Comments

One commenter noted that the exclusion of HIEs is overbroad, stating that if SAMHSA wants to ensure that organizations that access a patient's information under a general designation only do so for purposes of caring for the patient, it could adopt a provision that simply says an HIE can only use a general designation on its consent form if it has policies to ensure that participants obtain information under the general designation only for limited purposes, such as treatment, payment, or health care operations as defined under HIPAA.

SAMHSA Response

At this time, we do not believe this exclusion to be overbroad. As stated above, newly finalized language in § 2.31(a)(4)(ii) continues to allow patients to use a general designation in consenting to disclose their records to organizations that facilitate the exchange of health information. Specifically, if a recipient entity facilitates the exchange of health information or is a research institution, a written consent must include the name(s) of the entity and either the name of the individual or entity participants, 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 (e.g., "my treating providers"). We will, however, consider this suggestion in the future if we find the current language to be limiting to patients.

E. Prohibition on Re-Disclosure (§ 2.32)

SAMHSA is finalizing this section as proposed.

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 in the 2017 final rule. 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 redisclosure provision only applied to information from the record that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a SUD by a part 2-covered provider. The prohibition still allowed 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 since heard from the provider community that this section of the regulation 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 SUD. This activity is operationally burdensome and not the intent of the 2017 final rule. As noted in Section IV.C. above, SAMHSA has proposed to modify § 2.12 to clarify that the recording of information about an SUD and its treatment by a non-part 2 provider is permitted and not subject to part 2, and that the non-part 2 provider may segregate or segment any patient record previously received from a part 2 program to ensure that she can distinguish them from her own patient records created following clinical encounters. Therefore, a downstream non-part 2 provider would not need to redact SUD information in its own records in an effort to comply with part 2, provided that any outside patient record previously received from a part 2 program or other lawful holder is segregated or segmented.

To ensure that downstream non-part 2 providers 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), SAMHSA proposed 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 (84 FR 44574). Specifically, we proposed to remove "information in" and "that identifies a patient as having or having had a SUD 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 added language to specifically state that only the part 2 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 (84 FR 44574).

The comments we received on the proposed amendments to § 2.32 and our responses are provided below.

Public Comments

Several commenters supported our proposal to streamline the redisclosure language in § 2.32, stating that the change would reduce counterproductive provider burden, decrease confusion, and would also support enhanced, whole-person care coordination for the benefit of the patient. One commenter specifically noted that because of the way the provision was previously worded, providers would redact critical patient information for fear of violating Part 2, leading to gaps in care. One commenter, while supporting the proposal, noted that the need to revise this language may be limited, because of the ability to use an alternative short form of the notice which was implemented in the 2018 final rule. Some commenters, while supporting the proposal, requested additional clarification on how patient confidentiality will be assured.

SAMHSA Response

We thank the commenters for their support. As noted above, part 2 records will continue to be protected by part 2: The changes in § 2.32 of the final rule merely provide clarity so that non-part 2 providers will better understand that they do not need to redact patient information from their own clinical records that are not protected by part 2.

Thus, we believe that patient confidentiality will still be appropriately maintained under this proposal.

Public Comments

Some commenters opposed our proposal to streamline the redisclosure language in § 2.32, noting confidentiality concerns and potential negative impacts to clinical decision-making. One commenter specifically stated that patients would be reluctant to sign a consent for disclosure of their records for legitimate reasons, knowing that once the medical records are sent out, they can be disseminated without the patient's consent.

SAMHSA Response

SAMHSA does not believe that the final rule on § 2.32 changes the basic consent requirements in the regulations. Instead, as stated above, the change in § 2.32 simply streamlines the required "Notice" language, to ensure that non-part 2 providers are not burdensomely seeking to redact large amounts of text from a patient's general medical record that is not protected under Part 2. In addition, SAMHSA does not anticipate any adverse impact from the final rule on § 2.32 on clinical decision making. In fact, the more information received by a downstream clinician in a record that is not redacted, the better informed that clinician will be, thereby facilitating better informed patient-clinician decisions.

Public Comments

A few commenters specifically stated that they did not support this proposal because of the corresponding changes being proposed to § 2.11. These commenters asserted that information conveyed from a part 2 program to a non-part 2 provider for treatment purposes with the consent of the patient would no longer be protected by the Part 2 rules and only subject to HIPAA, which has fewer protections and could lead to medical care discrimination and increased legal prosecution.

SAMHSA Response

As stated above, under this rule, any record disclosed by a part 2 program to a non-part 2 provider will still be subject to part 2, and the recipient's own clinical record might also become subject to part 2 if the received record is wholly incorporated into the non-part 2 provider's own patient record. Thus, § 2.33 would continue to apply to records in these instances.

Public Comments

A few commenters, although supporting the intent of the proposal, noted difficulties in operationalizing the provision with EHRs. These commenters recommended that future regulations clarify the re-disclosure requirements, and recognize the existing challenges within both paper and electronic environments. The commenters encouraged SAMHSA to provide better examples and guidance for successfully implementing the redisclosure requirements. One commenter specifically asked SAMHSA to engage in pilot testing and evaluation of relevant standards and technologies and suggested establishing a temporary safe harbor for enforcement while the technical issues are studied. This commenter also asked that, given the difficulty of distinguishing part 2 records from general medical information, SAMHSA consider lesser penalties for "good faith" errors in contrast to malicious or other intentionally wrongful disclosures.

SAMHSA Response

In the 2018 final rule, SAMHSA explicitly adopted an abbreviated notice that is 80 characters long to fit in standard free-text space within health care electronic systems (83 FR 240). SAMHSA has not proposed any change to this abbreviated notice language in § 2.32; thus, stakeholders may continue using this language in their EHR systems. As we previously noted in the 2018 final rule, SAMHSA acknowledges that there may be technical issues connected to compliance with § 2.32 which will require future guidance to resolve. Nevertheless, SAMHSA believes that the current final rule on § 2.32 involves an appropriate balance of interests at present. SAMHSA will continue to work with stakeholders, as needed, to provide guidance in the future.

Public Comments

One commenter stated that the proposal will need to be enforced to be effective, citing examples of third parties re-disclosing records, even though all the pages are stamped with the non-re disclosure statement.

SAMHSA Response

We also believe enforcing part 2 is important to protect confidentiality of patients. We will continue to pursue enforcement of this and other provisions under part 2.

Public Comments

A few commenters asked us to take the proposal further, by completely

eliminating the redisclosure prohibition, stating that the statute does not require it. Commenters noted that downstream redisclosures would fall under HIPAA protections, which are robust in nature and familiar to those entities and individuals who would be engaging in the redisclosures.

SAMHSA Response

As stated in the 2017 final rule, while the statute may not be explicit with regard to all provisions in 42 CFR part 2, the statute directs the Secretary to provide for such safeguards and procedures as, in the judgment of the Secretary, are necessary or proper to effectuate the purposes of this statute, to prevent circumvention or evasion thereof, or to facilitate compliance therewith (82 FR 6089). At this time, SAMHSA believes that § 2.32 is still necessary, on balance, to appropriately protect the confidentiality of patients.

We do anticipate making further revisions to part 2 in the future, in order to implement the relevant provisions of the CARES Act, and we will review the status of § 2.32 in any future rulemaking.

Public Comments

One commenter recommended that SAMHSA add notice language to § 2.32, to reinforce that the non-part 2 provider/entity has received the part 2-protected SUD information for the permissible purpose of improving service delivery for the patient, and that although unauthorized redisclosure of part 2-protected information is prohibited, this information should be used as intended for the permissible purpose.

SAMHSA Response

The final rule at § 2.32 does not specify particular purposes for which part 2 protected records must be used, once the patient consents to such use. We believe it is best to empower patients to specify the terms for a limited disclosure, rather than adding compulsory requirements for the use of disclosed records, which might be confusing and could cause providers to limit the disclosure of important information intended to be conveyed by the patient.

F. Disclosures Permitted With Written Consent (§ 2.33)

In response to comments received on the proposed rule and the CARES Act provision incorporating into 42 U.S.C. 290dd-2 the HIPAA Privacy Rule definition of health care operations, which includes care coordination and case management activities, SAMHSA is

modifying this section of the rule from what was proposed, to add care coordination and case management as an example of an activity for which a lawful holder may make a further disclosure to its contractors, subcontractors and/or legal representatives, in support of health care payment or operations. In order to avoid confusion about the extent of § 2.33(b), SAMHSA has also deleted from the regulatory text the statement that “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.”

While we did not specifically propose to include care coordination and case management in the list of activities under § 2.33(b), the NPRM addressed the issue of how to facilitate these types of services, and we received public comments on this point. More recently, Congress passed the CARES Act, which expressly permits disclosure of Part 2 information for these very purposes. To the extent that there may be a concern that we did not formally and specifically solicit public comment on listing care coordination and case management in § 2.33(b), we believe that further notice and comment on this matter is unnecessary. The Department’s statements in the NPRM elicited comments on this issue, and the subsequent passage of the CARES Act would otherwise effectuate § 2.33(b) of this final rule starting March 27, 2021. Additionally, permitting disclosures under § 2.33(b) for case management and care coordination services in this final rule will have the effect of granting providers, part 2 programs and lawful holders more time in which to establish processes for carrying out these essential services in accordance with the requirements of this final rule and the CARES Act provisions. Therefore, the Department finds good cause to forego notice and comment on whether care coordination and case management activities should be included in the illustrative list of permissible payment and health care operations activities under 2.33(b). 5 U.S.C. 553(b)(B)(an agency is exempt from the notice and comment requirements of the Administrative Procedure Act if the agency “for good cause finds . . . notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest”).

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 in the regulatory text a list of 17 specific types of permitted categories of 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 have believed that a particular activity was not permissible unless explicitly identified within the regulatory text. Therefore, to clear up any remaining confusion, SAMHSA proposed 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, SAMHSA proposed to add the following examples of permissible activities that SAMHSA considers to be payment and health care operations activities to § 2.33(b):

- 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 proposed to add “other payment/health care operations activities not expressly prohibited” in this provision to the end of the list. SAMHSA also again clarified in the preamble to the proposed rule (84 FR 44575) that § 2.33(b) was not intended to cover disclosures to contractors, subcontractors, and legal

representatives for the purposes of care coordination or case management, and disclosures to carry out such purposes were not permitted under this section. We noted that this policy differs from the HIPAA Privacy Rule, under which ‘health care operations’ encompasses such activities as case management and care coordination. SAMHSA 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). We stated in the proposed rule that 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, we noted that several of the proposals to revise other sections of part 2 in this rulemaking would help to facilitate coordination of care, as under § 2.12 (Applicability). However, as discussed above, due to recent CARES Act amendments as well as public comments, SAMHSA has decided to include care coordination and case management in the illustrative list of examples of payment and health care operations activities for which disclosures may be made under § 2.33(b).

At this time, we note that this rule provides transitional regulations until such time as implementing regulations for § 3221 of the CARES Act come into effect. In future rulemaking, we will consider further revisions to § 2.33, as needed to implement relevant provisions under the CARES Act.

The comments we received on the proposed amendments to § 2.33 and our responses are provided below.

Public Comments

Several commenters expressed support for the proposed changes, saying that moving the list to the regulatory text reduces confusion; appropriately acknowledges the modern health care landscape and the role of third-party entities in facilitating access to SUD treatment services; and provides a helpful guide as to what information may be shared and for what purposes. One commenter said that SAMHSA is trying to do what it can to enable appropriate disclosures for the sake of part 2 program operations and coordination of care and still reasonably protect the privacy of the part 2 patient. Another appreciated the addition of the 18th item, “other payment/health care operations activities not expressly prohibited,” to clarify that the list is not exhaustive. One commenter supported the changes but said that adding these fairly numerous exceptions will add

greater complexity to a regulation with which providers and payers already struggle. Other commenters supported the change but requested that SAMHSA include care coordination and case management in the list of permitted activities, as discussed further below.

SAMHSA Response

We thank the commenters for their support and insights about the change. We address in a subsequent answer below public comments requesting the addition of care coordination and case management to the list of permitted activities in § 2.33(b).

Public Comments

One commenter supported the changes to § 2.33 but requested additional clarification on how patient confidentiality will be assured.

SAMHSA Response

We refer the commenter to § 2.33(c), which outlines contract provisions for disclosures made under § 2.33(b), ensuring that that contractors, subcontractors or voluntary legal representatives who receive information pursuant to this section are fully bound by the part 2 regulations, among other requirements. We also refer the commenter to § 2.13(a), which states that any disclosures made under the regulations must be limited to that information that is necessary to carry out the purposes of the disclosure. As we have previously stated, to comply with § 2.13, lawful holders should ensure that the purpose section of the consent form is consistent with the role of or services provided by the contractor or subcontractor (e.g. “payment and health care operations”) (83 FR 244).

Public Comments

One commenter requested additional clarification that a qualified service organization (QSO) under § 2.11 can provide the same health care operation services that will now be codified in § 2.33 for contractors of non-part 2 programs.

SAMHSA Response

A QSO is an individual or entity who provides services to a part 2 program consistent with a qualified service organization agreement (QSOA). Examples of services provided by QSOs include data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, population health management, medical staffing, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group

therapy. We believe many of these activities would overlap with those articulated in § 2.33(b) related to information disclosures to a lawful holder’s contractors, subcontractors and legal representatives for the purposes of payment and/or health care operations.

Public Comments

One commenter recommended that SAMHSA clarify the term “information which is necessary to carry out the stated purpose” in regard to activities related to training of student trainees and healthcare professionals; business planning and development; management; and customer services. Alternatively, the commenter suggested that the regulations could require that these individuals use the part 2 information in a manner that is compliant with the HIPAA privacy regulations.

SAMHSA Response

Under § 2.33(b), disclosures to a lawful holder’s contractors, subcontractors and legal representatives for payment and health care operations must be limited to that information which is necessary to carry out the stated purpose of the disclosure. This provision helps to ensure that information is not shared more broadly than the purposes for which the patient consents. Thus, disclosures for any of the activities under § 2.33(b) must be limited to that minimal amount of information that is truly necessary to carry out the purpose of the specific health care and payment operations activity intended. Likewise, under § 2.13(a), information disclosed under the part 2 regulations must be limited to that information which is necessary to carry out the purpose of the disclosure. To comply with § 2.13, we have previously stated that part 2 programs and lawful holders disclosing information under § 2.33(b) should ensure that the purpose section of the consent form is consistent with the role of or services provided by the contractor or subcontractor (e.g. “payment and health care operations”) (83 FR 244).

At this time, we note that this rule provides transitional regulations until such time as implementing regulations for § 3221 of the CARES Act come into effect. In future rulemaking, we will consider making further revisions to § 2.33, consistent with the CARES Act.

Public Comments

A few commenters requested additional clarity on the types of activities that are permitted. Commenters suggested expanding the list and providing examples of

permitted activities, as well as describing expectations for activities that are not on the list. One commenter suggested that, rather than listing the 17 activities, the language “unless explicitly prohibited” would provide more clarity. A few commenters said SAMHSA should be clearer that the list is not all-inclusive.

One commenter asked that several items on the list of permitted activities be clarified to include specific activities. The commenter asked that the second item on the list, clinical professional support services (*e.g.*, quality assessment and improvement initiatives, utilization review and management services), be further clarified to include the calculation of quality measures and creation of appropriate benchmarks; that the third item on the list, patient safety activities, be further clarified to include determination of drug-drug interaction and notification of a prescriber and pharmacy provider if a medication is being prescribed that would be contraindicated for an individual receiving MAT; that the fourth item on the list, activities pertaining to training, practitioner assessment and practitioner plan performance, and training of non-health care professionals, be clarified to permit health plans and their contractors to make site visits and review records of a part 2 program provider as part of the accreditation process and reaccreditation process; and that the 13th item on the list, business planning and development, including the development or improvement of methods of payment or coverage policies, include activities related to the development and implementation of delivery system and payment reform. One commenter asked SAMHSA to clarify that this section would allow part 2 claims information to be utilized to evaluate whether an individual is an appropriate candidate for a prescriber or pharmacy restriction program.

SAMHSA Response

SAMHSA is finalizing in regulatory text under § 2.33(b) an illustrative and lengthy set of categories of activities for which lawful holders would be allowed to further disclose the minimal information necessary to contractors, subcontractors, or legal representatives for payment and health care operations. SAMHSA expects that this list will provide needed direction and guidance to stakeholders about the reasons for which information may be disclosed under this section, and its broad language should also provide flexibility for stakeholders to carry out necessary activities within each category to

provide part 2 patients with quality care. SAMHSA believes the categories are largely self-explanatory, and we decline to list examples of all the potential activities that fit within each category, given the variation in and the evolving nature of the health care delivery system. SAMHSA does expect that additional payment and health care operations activities beyond those explicitly named would be permitted under § 2.33, and thus we are finalizing our proposal to add a final item to the list, indicating that other payment and health care operations activities not expressly prohibited are also allowed. The final item is intended to help ensure that stakeholders understand the list is not exclusive.

Public Comments

A commenter asked if activities described in § 2.33(b)(1)–(3) are only permissible with written patient consent, and if any of these activities fall under § 2.12(c)(3). The commenter believed a part 2 program needs consent before it shares information for operational activities such as supervision, training, quality assurance, peer review, etc. with an entity having direct administrative control over it.

SAMHSA Response

The activities listed in § 2.33(b) require a patient’s consent to disclose his or her information for payment and health care operations. However, the part 2 regulations provide leeway for part 2 programs to share information within their larger health care organizations. Section 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 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.” 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.” Additionally, 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. Further, information may be shared for audit and evaluation purposes under new § 2.53(a)(1)(iii) and (b)(2)(iii) with

entities that have direct administrative control over part 2 programs.

Public Comments

Several commenters opposed the change, stating that it has the potential for strong negative impacts to patients who may not fully understand to what they are consenting; would greatly expand the number of redisclosures without consent, including to entities that are not involved in direct patient care; and make it more difficult to respond to emerging practices that threaten patient privacy. One commenter said that aside from treatment purposes and a business associate-styled exception (with protections) for EMR and HIE vendors, disclosures should generally require written consent of the patient. Another said that the proposed change would permit disclosure without consent so broadly as to undercut the idea of protections and make the rules unenforceable as injured parties would not be able to identify who violated the rules. One commenter said it may be more appropriate for the agency to provide the illustrative list of activities that fall under “payment and health care operations” as regulatory guidance instead of including it in the regulation itself, as publishing the list as guidance may enable providers to feel more comfortable participating in activities not explicitly listed, but important to providing coordinated patient care.

SAMHSA Response

SAMHSA recognizes that lawful holders of part 2 information have legitimate needs to disclose that information to contractors, subcontractors and legal representatives, which play an integral role in the management, delivery and payment of health care services. The list of permitted activities was initially finalized as guidance in the 2018 final rule preamble. 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. SAMHSA is now codifying the list in the regulatory text for added clarity. SAMHSA believes it has struck the correct balance between protecting patient confidentiality and ensuring that lawful holders involved in providing and paying for SUD treatment can reasonably function in today’s complex

health care delivery framework. While § 2.33(b) allows for disclosures to contractors, subcontractors and legal representatives for health care payment and operational activities, SAMHSA has also placed limits on disclosures of part 2 information to such entities for such purposes. Specifically, § 2.33(c) outlines contract provisions for disclosures made under § 2.33(b) ensuring that that contractors, subcontractors or voluntary legal representatives are fully bound by part 2, among other requirements.

Public Comments

A few commenters said that the activities included in the term “health care operations” are so wide-ranging that they could be interpreted as permitting activities that could harm SUD patients by potentially allowing protected SUD information to be disclosed to employers. Commenters recommended the inclusion of anti-discrimination protection language in this section.

SAMHSA Response

As we have previously indicated, promulgating rules that address discriminatory action is outside the scope of SAMHSA’s legal authority (83 FR 248). However, we refer the commenter to § 2.13(a), which states that patient records subject to the part 2 regulations may be disclosed or used only as permitted by the regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority. Further, §§ 2.64 and 2.65 describe required procedures and criteria for orders authorizing disclosures for criminal investigations of patients and for non-criminal purposes (such as a civil action).

Public Comments

One commenter said that although this section does not cover care coordination or case management, other clarifications in the proposed rule address those questions sufficiently.

SAMHSA Response

We appreciate this comment, but we also refer to our response below with regard to the addition of care coordination and case management to the list of permitted activities under § 2.33(b).

Public Comments

Many commenters objected to the exclusion of care coordination and case management under § 2.33(b) and asked SAMHSA to align its policy with the HIPAA privacy rule by including these

activities in the definition of health care operations, or to otherwise allow care coordination and case management to be included in the list of permitted activities. A few commenters specifically noted that SAMHSA has the authority under 42 U.S.C. 290dd–2 to enact this change. One commenter suggested these activities be reclassified as health coaching or other legitimate health plan operational activities in order to ensure the appropriate coordination of care, while another urged SAMHSA to adopt a specific care coordination exception to the consent requirement.

Commenters gave many reasons for objecting to the exclusion of care coordination and case management from the list of permitted activities. Some commenters said the current policy is harmful to individuals with SUDs because it increases the risk of negative drug interactions, medical errors, overdose, or death; creates delays in care or in the receipt of MAT; and maintains and reinforces the stigma of SUD. Other commenters stated that disallowing care coordination and case management from the list of permitted activities is inconsistent with best practices and incompatible with the way health care is delivered today, hindering the ability to provide comprehensive, integrated, coordinated care that decreases emergency room and inpatient services. Commenters emphasized that optimal, safe care requires access to a patient’s entire treatment history and current medications. Some commenters said that the current policy prevents insurers, Medicaid agencies, administrators, peer support organizations, and providers from making a more meaningful personal care impact and creates more difficulty in helping patients obtain better health outcomes.

A few commenters said the current rule causes confusion and administrative burden for providers as well as health plans that have difficulty obtaining written consent from enrollees, patients who must sign multiple consent forms, and other parties involved with the provision of health care. A few commenters also emphasized that the current policy is misaligned with HIPAA and that allowing for care coordination and case management under § 2.33(b) would ease administrative burden for entities subject to both part 2 and HIPAA. Another commenter said it would avoid the “slippery slope” of possibly expanding the proposed part 2 applicability changes to other non-part 2 lawful holders and for purposes

beyond TPO. A few commenters also said that established definitions of “care coordination” and “case management” do not refer to treatment, diagnosis and referral, but instead refer to more operational, or management-based activities.

Several commenters emphasized potential benefits of including care coordination and case management in the list of permitted activities, such as increasing access to integrated, whole-person care; improving treatment adherence and outcomes; enabling managed care organizations to more easily provide valuable supports to their beneficiaries with SUD; avoiding duplicative prescriptions; facilitating communication with appropriate community-based organizations; alleviating complex consent requirements; and lowering overall health care costs. Another commenter said that recovery should be coordinated to address self-care practices, family, housing, employment, transportation, education, clinical treatment for mental disorders and SUDs, services and supports, primary healthcare, dental care, complementary and alternative services, faith, spirituality, creativity, social networks, and community participation.

One commenter said that SAMHSA has offered no legal or policy basis for this unique definition and handling of care coordination and case management for SUDs. A few commenters felt that part 2 limits or prohibits sharing of SUD records for critical care coordination activities while allowing it for less essential payment and health care operations. One commenter emphasized that SUD treatment providers must be treated equally—or with parity—to other health care providers. Others observed that changing the current policy would be consistent with the proposal’s goals of improving appropriate information flow and integrated care and is philosophically aligned with CMS’ and HHS’ broader efforts to create a more integrated and efficient care delivery system.

SAMHSA Response

SAMHSA understands and acknowledges the commenters’ concerns. SAMHSA recognizes that care coordination activities have numerous benefits described by the commenters, including the ability to protect patient safety, improve quality of care, and lower costs. SAMHSA also recognizes, consistent with commenter feedback, that many activities involving care coordination and case management are operational in nature, and distinguishable from the direct

disclosure of a treatment record from one provider (e.g., a part 2 program) to another (e.g., a non-part 2 primary care physician) for the purpose of treatment and diagnosis.

Because of the public comments that SAMHSA received on this issue in the proposed rule and the CARES Act amendments incorporating into 42 U.S.C. 290dd–2 provisions permitting disclosure of part 2 information for care coordination and case management activities, SAMHSA has decided to add care coordination and case management to the list of examples of permissible activities under the heading of payment and health care operations in § 2.33(b) in the regulatory text of the final rule. Under the final provision, a lawful holder who receives an SUD record subject to a patient's written consent may further disclose that record to its contractors, subcontractors, and/or legal representatives, for the purpose of carrying out care coordination or case management services in support of health care payment or operations. In order to avoid confusion about the extent of § 2.33(b), SAMHSA has also deleted from the regulatory text the statement that “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.” The revised, final rule language of § 2.33(b), taken on its face, applies to a patient's consent to a disclosure of his records for the purpose of payment and/or health care operations.

With regard to the revised, final rule language of § 2.33(b), we also note that the passage of the CARES Act by Congress will result in a major change to the authorizing statute, and will provide far greater flexibility for patients and health care providers to share SUD records than currently allowed under 42 U.S.C. 290dd–2. The revised, final rule language of § 2.33(b) represents an interim and transitional step towards more flexibility in consented-to disclosures for purposes of care coordination and case management, consistent with the realignment to the HIPAA privacy rule that is required by several provisions under the CARES Act. Again, HHS intends to publish a new NPRM and subsequently to issue final implementing regulations for the CARES Act in the future.

In the interim, note also that several other sections of this final rule, particularly at § 2.11 and § 2.12, separately will help to facilitate instances in which a care coordination activity is intermediated by a disclosure

directly from a part 2 program to a non-part 2 provider for the purpose of treatment.

Public Comments

A few commenters said it is unclear whether care coordinators can be considered to have a treating provider relationship with the patient for purposes of the general designation option, and/or that they should be recognized as having a treating provider relationship for the purposes of part 2. One commenter said that this ambiguity is particularly challenging for accountable care organizations (ACOs), as patients may be passively attributed to the ACO and may not recognize the ACO's role in coordinating his or her care. The commenter requested that SAMHSA clarify under what circumstances an ACO can use disclosed part 2 information when the patient often is unaware that he/she is participating in the ACO due to passive attribution.

SAMHSA Response

As SAMHSA has previously indicated, individuals and entities that meet the definition of having a treating provider relationship with the patient are considered treating providers. The determination is fact-specific. (82 FR 6082). SAMHSA declines to explicitly broaden the term “treating provider relationship” to include all persons and entities that engage in any form of care coordination activity in this final rule. However, SAMHSA also has noted previously (82 FR 6085) that the definition of “treating provider relationship” is sufficiently broad to cover the necessary components of a patient's care team. SAMHSA may provide further sub-regulatory guidance in the future with regard to ACOs, if further clarification is needed.

Public Comments

A few commenters suggested that SAMHSA allow part 2 records to be disclosed for the purposes of care coordination with specific written patient consent that is clear and understandable. A few commenters said that SAMHSA could permit the use of a one-time, generalized consent that would allow for the disclosures and redisclosures for treatment, payment, and health care operations purposes to HIPAA-covered entities and part 2 programs. Similarly, a commenter emphasized that allowing general consent to share SUD information with caregivers for “other treatment” purposes, including placement and care coordination, would reduce the significant administrative burden

associated with generating a specific consent prior to each instance that this information is shared with caregivers. Another commenter recommended that SAMHSA revise 42 CFR 2.33(b) to allow lawful holders that receive part 2 records pursuant to a patient's consent to disclose such information to their contractors, subcontractors, and legal representative for “all purposes authorized by the patient.” One commenter urged SAMHSA to adhere to the American Academy of Family Physicians' (AAFP's) policy on Patient/Physician Confidentiality regarding the privacy of medical information, and specifically that third-party payer and self-insured employer policies and contracts should explicitly describe the patient information that may be released, the purpose of the information release, the party who will receive the information, and the time period limit for release.

SAMHSA Response

As explained above, SAMHSA has made a change to the regulatory text of § 2.33(b), to add care coordination and case management to the list of examples of permissible disclosures under the heading of payment and operations. Under the final provision, a lawful holder who receives an SUD record subject to a patient's written consent may further disclose that record to its contractors, subcontractors, and/or legal representatives, for the purpose of carrying out care coordination or case management services in support of health care payment or operations. SAMHSA believes that this revision to § 2.33(b) will strike the appropriate balance in facilitating disclosures with patient consent, for the purpose of operational care coordination and case management activities. SAMHSA believes that it is beyond the scope of the current rule-making to address AAFP's policy, with regard to instituting new requirements for third-party payer and self-insured employer policies and contracts, and thereby describing and limiting any corresponding release of information from patient records.

Public Comments

One commenter expressed concern that SAMHSA has also continued to exclude diagnosis, treatment, and referral to treatment from the proposed rule's definition of health care operations, and urged SAMHSA to further revise the rule to include these critical activities in its definition of health care operations.

SAMHSA Response

SAMHSA is making a change to § 2.33(b) in the final rule addressing these issues, as described above.

Public Comments

A few commenters advocated that 42 CFR part 2 be brought into full alignment with HIPAA, saying it would streamline consents; reduce barriers to data sharing, care coordination and treatment; and maintain appropriate privacy protections. Commenters emphasized that full alignment with HIPAA would better reflect current health care operations as well as legal and social healthcare policy. One commenter said that the HIPAA privacy framework includes protections for healthcare records, conversations with providers about care decisions or treatment, and personal information, such as billing information. Another commenter noted that providers have years of experience with the HIPAA framework, have processes in place to ensure that coverage and treatment information is protected, and face the risk of enforcement penalties under HIPAA. A few commenters urged SAMHSA to allow part 2 records to be shared without re-disclosure restrictions as long as any re-disclosures are for similar treatment, payment and health care operations purposes, or alternatively that SAMHSA include the sharing of medical records from part 2 providers with HIPAA-covered providers, health plans and care coordination entities without patient consent, including the exchange of that information through Health Information Exchanges. Another commenter recommended that if such streamlining cannot be accomplished, SAMHSA provide further guidance to industry regarding ways in which important patient care objectives can still be achieved despite the restrictions.

SAMHSA Response

Due to its targeted population, part 2 provides more stringent federal protections than most other health privacy rules, including HIPAA. In light of the part 2 authorizing statute and its intent, SAMHSA is unable to create the alignment suggested by the commenters. However, in this final rule, SAMHSA does make numerous revisions to the part 2 regulations that will improve information sharing among a patient's treating providers, which should enhance the ability to coordinate care and better serve patients receiving treatment from part 2 programs. In this regard, we also note that the current rule provides a transitional standard until

such time as implementing regulations for § 3221 of the CARES Act come into effect. In future rulemaking, we will consider making additional revisions to § 2.33, as needed to implement relevant provisions under the CARES Act.

Public Comments

One commenter suggested clarifying that a patient does not need to complete the "purpose" section of a 42 CFR part 2-compliant consent form for it to be a valid authorization. The commenter said that denying a patient-directed release of information because the patient has failed to complete this section is not appropriate or consistent with SAMHSA's commitment to "patient choice in disclosing information."

SAMHSA Response

We disagree with the commenter. Section 2.31(a)(5) requires the consent to include the purpose of the disclosure. Section 2.31(b) states that a disclosure may not be made on the basis of a consent which on its face substantially fails to conform to any of the requirements set forth in § 2.31(a).

Public Comments

Several commenters offered ideas for topics that future regulations or guidance could address, including phone screenings; new care models; the use of digitized voice consent; and a templated, plain language part 2 record consent form that could be used to better standardize disclosures, provided in an electronic format that would allow populated data to be easily integrated into information management systems.

SAMHSA Response

We thank the commenters for their suggestions and will consider these ideas for future guidance.

G. Disclosures To Prevent Multiple Enrollments (§ 2.34)

SAMHSA is finalizing this section as proposed.

In the 2017 final rule, SAMHSA modernized § 2.34 by updating terminology and revising corresponding definitions. Section 2.34 permits, with consent, disclosure of patient records to a withdrawal management or maintenance treatment program within 200 miles of a part 2 program. After considering 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 MAT program, methadone is a safe and effective treatment for SUD, including opioid use disorder (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 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 proposed 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 proposed to amend § 2.34(b) to include the use of central registry information to coordinate care with a non-part 2 program. In addition, we proposed to add a new subsection (d) to specifically permit non-member treating providers to access the central registries. Previous subsection (d) would be redesignated 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.

The comments we received on the proposed amendments to § 2.34 and our responses are provided below.

Public Comments

Many commenters believed the proposed changes will prevent duplicative prescriptions, avoid adverse drug events, ensure patient safety, foster care coordination, and improve care quality.

SAMHSA Response

SAMHSA appreciates the comments and agrees that the finalized changes will give all providers with a treating relationship important information for treating patients with SUD, thereby increasing coordination and quality of care and improving patient safety.

Public Comments

A few commenters expressed concern that the proposed changes, if finalized, would reduce patient privacy and increase stigma and harm. Some commenters drew a distinction between changes proposed in § 2.36 and changes proposed in this section, noting that sharing information from central registries would infringe upon patient privacy protections in a way that contravenes 42 CFR part 2. One commenter expressed concern that the proposed changes are unnecessary and that medication information can be gathered through drug screens.

SAMHSA Response

SAMHSA is committed to improving the lives of people living with SUD, and individuals with SUD face real stigma. We believe that allowing medical professionals with a treating provider relationship access to central registries will improve the quality and safety of care for these individuals. We also believe that increasing care coordination and information access within an individual’s care team will reduce stigma by giving providers accurate and comprehensive information about a patient’s medical needs. We appreciate commenters’ concerns regarding patient privacy and remain dedicated to protecting information for individuals with SUD. SAMHSA believes that privacy cannot come at the cost of patient care and safety, and the proposed changes seek to balance the critical importance of patient confidentiality with the vital information required for medical professionals to provide the highest quality care to individuals with SUD. We also note that central registries already exist as defined in § 2.11 and the proposed changes in this rule would not create new registries. SAMHSA acknowledges that some information can be obtained from patient drug screens. However, accurate dosing and frequency of medications cannot be obtained from drug screens and these types of screens do not offer a reliable substitute for the proposed changes.

Public Comments

A few commenters in §§ 2.34 and 2.36 expressed concern about the concept of central registries, and noted that they

were opposed to requiring patients with SUD to be listed on a registry.

Several commenters requested clarification on the process to obtain consent for the proposed changes. Other commenters requested clarification on how the proposed changes would or would not compel corresponding changes in state law to permit access to central registries.

A few commenters requested clarification on the privacy protections afforded to information obtained by non-OTP providers from central registries if the information in the non-OTP record is not segmented. Some of these commenters also asked if the access to central registries was limited to physicians or open to other health care professionals with a treating provider relationship such as physician assistants or nurse practitioners.

SAMHSA Response

As noted earlier, SAMHSA understands the concerns of these commenters and would like to clarify that central registries as defined under § 2.11 already exist within OTPs and are used solely for the purpose of maintaining health care information. The proposals within this section would not create new requirements that compel patients with SUD to register on any lists.

SAMHSA anticipates that OTPs may update existing consent forms to include new language regarding information shared with non-OTP treating providers, or create new consent forms for this purpose. It is SAMHSA’s understanding that while many state laws do not inherently prevent access to central registries, some states may consider legal updates to ensure that non-OTP providers are not expressly prohibited from such access.

We appreciate commenter questions regarding the privacy protections afforded to information shared with non-OTP providers. Central registry information consists primarily of basic patient contact information and medication and dosage information limited to any treatment an individual is receiving from that OTP. Any information recorded by a non-OTP provider in her own practice’s patient record originating from a central registry query would be similarly limited. We anticipate that a non-OTP provider would discuss a patient’s SUD treatment history at a specific OTP prior to querying that OTP’s central registry. Therefore, any information obtained from the central registry query will supplement information provided by the patient in that encounter with the non-OTP provider. While SAMHSA

does not limit central registry queries to physicians, any non-OTP providers including physicians and non-physician (i.e. nurse practitioners, physician assistants) must demonstrate a treating provider relationship in accordance with relevant state law prior to querying a central registry.

Public Comments

A few commenters noted that while they are supportive of the proposed changes to permit non-OTP providers access to central registries, they would prefer the language in § 2.34 to require central registries to report to non-OTP treating providers. A few commenters expressed a preference for requiring such reporting without patient consent to ensure information accuracy, noting that permitting such reporting does not go far enough to protect patient safety. One commenter suggested that Part 2 programs be required to undertake such reporting in addition to central registries.

SAMHSA Response

We appreciate these comments and understand concerns that these proposed changes offer maximum impact for patient safety and information accuracy. Central registries vary widely. Some states may operate robust central registries while others may have more limited capabilities or may not operate a central registry at all. Given this variation, it is infeasible to require central registries or part 2 programs to report to external non-part 2 providers. Furthermore, SAMHSA has no authority under 42 U.S.C. 290dd-2 to impose such a requirement and declines to do so at this time.

Public Comments

One commenter recommended that SAMHSA utilize existing health information exchanges or networks to coordinate queries to central registries.

A few commenters recommended that SAMHSA establish minimum standards for central registries and require OTP participation in a central registry. These commenters noted that while the proposed changes will improve care coordination and patient safety, the lack of standardization and wide variation across central registries creates challenges for all providers treating patients with SUD. Some of these commenters stated that they were not aware of any central registries in their area even though they were aware of OTPs providing SUD services and requested that SAMHSA reconsider the role of central registries.

SAMHSA Response

We will consider these suggestions and continue to assess opportunities to improve the operational efficiency and efficacy of central registries.

H. Disclosures to Prescription Drug Monitoring Programs (§ 2.36)

SAMHSA is finalizing this section as proposed.

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.⁶ Forty-nine states, St. Louis County, Missouri⁷ 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.⁸ 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 PDMP⁹ 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.¹⁰ Studies have shown that states that have implemented such a requirement have seen declines in overall opioid prescribing, drug-related hospitalizations, and overdose deaths.¹¹

⁶ 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>.

⁷ 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.

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.

⁹ 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>.

¹⁰ 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/datavisualizations/2018/when-are-prescribers-required-to-use-prescription-drug-monitoring-programs>.

¹¹ 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.¹² 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.¹³ 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.¹⁴ 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.

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 proposed to add a new section § 2.36, permitting part 2

¹² 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/datavisualizations/2018/when-are-prescribers-required-to-use-prescription-drug-monitoring-programs>.

¹³ 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.

¹⁴ 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>.

programs, OTPs and other lawful holders to report the required data to their respective state PDMPs when dispensing medications with 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 the proposed provision 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 § 2.65 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.

We note that, under § 3221(k) of the CARES Act, it is the sense of Congress that any person treating a patient through a program or activity with respect to which 42 CFR part 2 protections apply is encouraged to access the applicable PDMP when clinically appropriate. In future rulemaking, we will consider the possibility of making revisions to § 2.36, as needed to implement relevant

provisions under the CARES Act. The comments we received on the proposed new provision of § 2.36 and our responses are provided below.

Public Comments

Many commenters supported the proposed changes, noting that PDMPs are an important tool for improving care coordination and safety for patients with SUD and that completeness of information is critical for all providers treating patients with SUD. Several commenters believed that this proposal will reduce deaths from adverse drug interactions. A few other commenters noted that many physicians and health care professionals are not aware that PDMPs do not currently contain comprehensive information on patient medications and they believed that this proposal is essential for improving patient care and safety, particularly for individuals receiving MAT.

SAMHSA Response

We appreciate the supportive comments and agree that the proposal will improve the quality and safety of care for individuals with SUD.

Public Comments

Many commenters opposed the proposed changes and expressed concerns about the potential breach of privacy patients may face and noted specific concerns regarding stigma, discrimination, and decreased likelihood of seeking treatment as a result of the proposed changes.

SAMHSA Response

As stated previously, SAMHSA is committed to improving the lives of people living with SUD, and individuals with SUD face real stigma. We believe that increasing care coordination and information access within an individual's care team will reduce stigma by giving providers accurate and comprehensive information about a patient's medical needs.

Public Comments

One commenter expressed concern about PDMP data being utilized for pre-employment physical examinations and Department of Transportation medical examinations and requested clarification on the appropriateness of PDMP data for occupational health purposes.

One commenter questioned the language in the proposed changes that includes medications prescribed and dispensed, noting that providers report only dispensed medications and not prescribed medications.

Several commenters requested SAMHSA to provide further clarification to states to legally permit OTPs to enroll in PDMPs in instances where doing so may currently contravene state PDMP laws or where state PDMP laws do not currently support OTP reporting.

Some of these commenters noted that state PDMP capabilities vary and some systems have more robust information than others. These commenters encouraged SAMHSA to work with states to facilitate PDMPs that can accommodate the proposed changes.

A couple commenters requested clarification on the patient consent process given the changing nature of PDMP capabilities. One commenter expressed concern that a patient's willingness to consent may change if the components or capabilities of a PDMP also change, and this should be taken into consideration in the proposed changes.

One commenter requested clarification for states as they work to modernize PDMPs, and expressed concern about unfunded costs to states to operationalize PDMPs for the type of reporting in the proposed changes.

A few commenters requested clarification on whether consent to disclose to PDMPs would be a separate consent or if it could be added to existing patient consent documentation. Some of these commenters also requested clarification on the level of specificity required if a patient requests a list of entities per § 2.31. A couple of commenters requested clarification as to whether additional consent is required regarding redisclosure and the sharing of part 2 information to each PDMP registered end user. One commenter requested clarification on the decision to support OTP disclosures to PDMPs but not for the purposes of care coordination or case management under § 2.33.

SAMHSA Response

SAMHSA acknowledges concerns about the use of PDMP data for occupational health decisions. It is not the intention of SAMHSA to permit the use of SUD information in pre-employment occupational health examinations, although SAMHSA does not have the statutory authority to control how states choose to utilize the data captured within their PDMPs. We note, however, that pursuant to § 2.13(a), patient records subject to the part 2 regulations may be disclosed or used only as permitted by the regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative

proceedings conducted by any federal, state, or local authority. While many state PDMPs require information solely upon dispensing, some state PDMP laws require prescribers to enter information at the point of prescribing and our language reflects the variation in these laws.

SAMHSA appreciates comments regarding PDMP capabilities and variations across states. Because PDMPs are operated by each state, it will be up to each state to update PDMP laws in a way that permits OTPs to enroll in PDMPs and maintain systems that accommodate the needs of registered users.

We understand commenter concern regarding the consent process. PDMPs are updated to provide maximum usability and information accuracy. Inherent in a patient's consent is the understanding that a PDMP database is continuously updated with current prescribing and dispensing information. Part 2 programs may consider periodic updates to their consent forms to reflect any substantial changes to their state PDMP.

SAMHSA appreciates the costs to states as they modernize and update PDMPs. While the proposed changes may require some state PDMPs to adapt or adopt new capabilities, we note that the goal of PDMPs is to provide accurate, timely information on prescribing and dispensing. The evolving nature of medical and pharmaceutical care requires routine maintenance and updates and we do not believe these proposed changes exceed those obligations. SAMHSA anticipates that OTPs may update existing consent forms to include new language regarding information shared with non-OTP treating providers, or create new consent forms for this purpose. We do not expect the proposed changes to require additional consent for redisclosure to each registered PDMP end-user.

Changes proposed under § 2.36 require that the patient specifically consent to the disclosure to a PDMP. This is distinct from disclosures for care coordination under § 2.33, which require only that the patient generally consent to the part 2 program making a disclosure for payment and/or health care operations activities.

Public Comments

Several commenters requested that patient consent not be required because of the potential adverse effects on safety if an individual declines treatment due to the PDMP consent requirement and/or provides incomplete or inaccurate information as a result of the consent

requirement. A few commenters requested that OTPs be required to report to PDMPs to provide the most complete information and to fill in gaps that may be created by varied PDMP usability and/or inconsistent standards and availability of central registry data.

SAMHSA Response

As stated previously, we appreciate these comments and understand concerns that these proposed changes offer maximum impact for patient safety and information accuracy. State operation of PDMPs and part 2 program operation of central registries vary widely. Furthermore, SAMHSA has no authority under 42 U.S.C. 290dd-2 to impose such a requirement and declines to do so at this time.

Public Comments

One commenter recommended leveraging the use of statewide HIEs and HINs to coordinate queries to central registries and PDMPs.

A few commenters recommended a national prescription drug monitoring database as an alternative to state-level PDMPs and central registries.

A few commenters noted that common industry standards for PDMPs would be valuable given their utility in fighting the opioid crisis. One of these commenters also noted that e-prescribing provides a valuable alternative to tracking opioid prescriptions. This commenter expressed concerns about the lack of interoperability between EHRs and PDMPs and noted that this could create barriers for clinicians attempting to use PDMPs in real-time during patient encounters.

One commenter recommended educating non-OTP providers as the proposed changes may bring individuals with SUD into contact with clinicians who are unfamiliar with OTP protocols, terms, benefits, and limitations.

One commenter recommended moving proposed changes related to PDMPs to § 2.31(a)(4)(B) to say, "such as an entity that facilitates the exchange of health information, prescription drug monitoring program, or a research institution."

A few commenters recommended notifying PDMP users that information related to medications dispensed from OTPs may still be incomplete as a result of patient consent requirements.

SAMHSA Response

SAMHSA appreciates suggestions from commenters to better facilitate the integration of PDMP reporting among OTPs. PDMPs are overseen by states, and SAMHSA does not govern their

operation. We agree that OTPs may find benefit in educating providers about PDMPs and expect that the registration process will inform registered OTP users about the specific regulations governing the use and capabilities of the PDMP within their state. We also believe that non-OTP providers may benefit from education on SUD to become familiar with the unique needs of the patients they treat who may be living with SUD.

Public Comments

Many commenters expressed specific concerns regarding law enforcement access to PDMPs and shared fears of increased criminal prosecution or adverse legal action for patients with SUD. One commenter requested clarification on how a request for information regarding a specific patient traceable by the law enforcement agency with oversight of the PDMP to an OTP provider would be outside the definition of "disclose" in § 2.11.

A couple of commenters noted that specific guidance from SAMHSA reiterating that law enforcement may not seek individual patient records without a court order may be reassuring for patients. Other commenters noted that even though 42 CFR part 2 requires a court order from law enforcement to obtain individual patient records, many state PDMPs do not currently require a court order which could open a backdoor for law enforcement access without immediate changes to state PDMP law. Several commenters noted that while law enforcement may be required to obtain a court order before seeking additional records, sensitive inferences can be made from prescription records alone.

One commenter suggested that states with law enforcement agency oversight of the PDMP should move the operations to a different agency authority. A couple of other commenters suggested the addition of anti-discrimination language within § 2.36 that would provide more explicit protections against insurance, health care, and legal discrimination.

One commenter expressed concern about state laws that penalize pregnant or parenting women with SUD and noted that OTP reporting to PDMPs would create a significant disincentive for those women to seek necessary treatment.

SAMHSA Response

SAMHSA understands concerns from commenters regarding law enforcement interaction with PDMPs. As stated previously, PDMPs are overseen by states and SAMHSA does not govern

their operation. While we appreciate concerns about the challenges faced by individuals with SUD, especially with regard to interactions with law enforcement, we believe 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. This robust data is critical for providers and prescribers to make accurate and safe decisions for patient care. As stated in our response to similar comments on anti-discrimination language in response to the 2018 Final Rule, promulgating rules that address discriminatory action is outside the scope of SAMHSA's current legal authority (83 FR 248). With this being said, note that we anticipate revisiting § 2.36 in future rulemaking to implement the CARES Act, and we will continue to consider the concerns about PDMPs and law enforcement in that context.

I. Medical Emergencies (§ 2.51)

SAMHSA is finalizing this section as proposed.

Under § 2.51, disclosures of SUD 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 (including, but not limited to, heart attack, stroke, overdose), 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 proposed to amend this section to address the impact of major¹⁵ and natural disasters, declared by state or federal authorities, on access to substance use treatment and services, in addition to the more common situation of an individual experiencing a “bona fide medical emergency.”

Disasters (e.g., hurricanes, wildfires) can present unique challenges for patients with SUDs, 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 stated in the 2019 proposed rule that we believe that it is necessary—and consistent with our 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 final rule, such an exception is finalized.

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 proposed to revise § 2.51(a) to facilitate expedient access to care for patients with SUDs during natural and major disasters. Specifically, SAMHSA proposed to authorize, under § 2.51(a), a part 2 program to disclose patient identifying information to medical personnel, without patient consent, as needed in the event of a natural or major disaster to deliver effective ongoing SUD services to patients in such disasters. Specifically, SAMHSA proposed that this medical emergency exception would apply only when a state or federal authority 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.

The comments we received on the proposed amendments to § 2.51 and our responses are provided below.

Public Comments

Many commenters supported the proposal to amend § 2.51 to include natural and major disasters within the meaning of medical emergency for which there would be an exception to the requirement of consent for disclosure of part 2 records.

SAMHSA Response

We thank commenters for their support.

Public Comments

One commenter requested clarification whether a disaster would qualify as a medical emergency for every impacted patient. The commenter requested further clarification whether the closed part 2 program would need to determine if it is a medical emergency for each patient.

SAMHSA Response

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. We note that consent should still be obtained if at all feasible. However, if the situation we describe above occurs, and the part 2 program is unable to obtain consent or to provide services, the part 2 program may consider the event a medical emergency and is permitted to disclose the part 2 records without patient consent. The exception would be rescinded when the part 2 program resumes operations.

Public Comments

One commenter recommended that SAMHSA develop further guidance on how patients and other medical personnel may be notified that the program is closed and unable to provide services or obtain consent. The commenter recommended that the guidance also include examples of how part 2 records may be disclosed to medical personnel in the event the program is closed. One commenter recommended that SAMHSA work with the HHS Office for Civil Rights to coordinate communication and outreach efforts regarding the proposals to § 2.51 to ensure that medical personnel and health information professionals are aware of the changes. One commenter also recommended that SAMHSA work with the HHS Assistant Secretary for Preparedness and Response (ASPR) and other federal and state agencies to communicate a clear “start” and “end” for these situations.

¹⁵ 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>.

SAMHSA Response

We appreciate the commenters' suggestions. We will consider potential future options, including issuing further guidance and outreach as well as partnering with other HHS agencies, to ensure that medical personnel and other professionals are aware of the changes to § 2.51.

Public Comments

One commenter requested clarification on whether medical personnel includes peer recovery support personnel, recognizing that peer recovery support is a part of SUD treatment.

SAMHSA Response

Under the authorizing statute at 42 U.S.C. 290dd-2(b)(2)(A), part 2 records may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency. As stated in the 2017 Final Rule, it is up to the health care provider or facility treating the emergency to determine the existence of a medical emergency and which personnel are needed to address the medical emergency. The name of the medical personnel to whom the disclosure was made, their affiliation with any health care facility, the name of the individual making the disclosure, the date and time of the disclosure, and the nature of the medical emergency must be documented in the patient's records by the part 2 program disclosing the information.

Public Comments

A few commenters requested that SAMHSA expand the definition of emergency for when disclosures to another part 2 program or SUD treatment provider is permitted. A few commenters noted that the proposal does not consider localized, serious events that could create similar barriers as a declared state or federal emergency. One commenter recommended allowing a discretionary determination that the Part 2 program is unable to provide services to the person or obtain consent due to a disaster. A few commenters recommended that providers who have a treating relationship should have the discretion to determine what constitutes an emergency. One commenter recommended that SAMHSA include "man-made" disasters, such as cyber-attacks when information systems and networks could be impacted. One commenter recommended that SAMHSA ensure the proposed changes during a natural disaster is aligned with HIPAA.

SAMHSA Response

We thank commenters for their suggestions. With regard to the request that a medical emergency be determined by the treating provider, SAMHSA clarifies that any health care provider who is treating the patient for a medical emergency can make that determination.

Public Comments

One commenter recommended expanding the proposal to include waivers from the part 2 requirements, safe-harbor from penalties and enforcement for entities who follow these processes in good faith and public health emergencies.

SAMHSA Response

We appreciate the commenter's suggestion. Under the proposed changes to § 2.51, an exception is allowed when normal policies and procedures for obtaining consent according to §§ 2.31 and 2.32 may not be operational due to a natural or major disaster. If the part 2 program is unable to obtain consent or provide services because the program is closed, then the part 2 program may disclose the records. We decline to explicitly name a safe-harbor provision, because the regulatory text describes the exception to the consent requirements. Immediately following disclosure, the part 2 program shall document, in writing, the disclosure in the patient's records, including the name of the medical personnel to whom the disclosure was made, their affiliation with any health care facility, the name of the individual making the disclosure, the date and time of the disclosure, and the nature of the medical emergency.

Public Comments

One commenter stated that waiting for a bona fide emergency to allow providers to share information may be too late for the patient's care and that treating providers should be able to share information for safe care. One commenter noted that if a part 2 program is closed, then they may not be able to disclose information.

SAMHSA Response

Providers may share treatment information with other providers with patient consent at any time. However, we do not have the authority to permit information to be disclosed without patient consent prior to the medical emergency under the authorizing statute at 42 U.S.C. 290dd-2(b)(2)(A). Therefore, providers may not share information without patient consent prior to the declaration of a state of emergency and prior to a part 2 program closing due to the disaster unless the

program meets another exception in this part.

J. Research (§ 2.52)

In response to comments received, SAMHSA is finalizing this section as proposed except for the proposed change allowing research disclosures to members of the workforce of a HIPAA covered entity.

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.

As stated in the 2019 proposed rule (84 FR 44577), § 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,¹⁶ 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 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

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

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 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 proposed 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 stated in the proposed rule that we believe 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 proposed two additional changes to the text of § 2.52(a). First, SAMHSA proposed 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 proposed 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 parts 50 and 56), subject to appropriate documentation of compliance with FDA regulatory requirements, and pursuant to authority under the Federal Food, Drug, and Cosmetic 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.

The comments we received on the proposed amendments to § 2.52 and our responses are provided below.

Public Comments

Many commenters supported the proposal to broaden part 2 disclosures for research purposes to include entities not covered by HIPAA or the Common Rule so long as the part 2 data is disclosed in accordance with the HIPAA Privacy Rule at 45 CFR 164.512(i).

SAMHSA Response

We thank commenters for their support.

Public Comments

Several commenters opposed the proposal. A few commenters felt that patient consent should be obtained before disclosing part 2 information for research purposes to entities not covered by HIPAA or the Common Rule. A few commenters felt that the proposed change will result in additional legal prosecution and discrimination. One commenter noted that it may make it difficult to identify a breach. One commenter recommended that SAMHSA clarify what level of protections non-HIPAA covered entities will be held to when part 2 data is disclosed for research purposes. The commenter suggested that sharing sensitive data with non-HIPAA covered entities should require IRB approval and if this is not possible then only the minimal amount of identifiable information as possible.

SAMHSA Response

We are seeking a balance between protecting the confidentiality of SUD patient records and ensuring that researchers can conduct critical research on SUD care and SUD populations. The proposed change to § 2.52 would align the requirements of part 2 around the conduct of research on human subjects with the HIPAA Privacy Rule, the Common Rule and other analogous requirements for the conduct of research on human subjects that may apply under other federal regulations. Specifically, part 2 data may be disclosed 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). The HIPAA Privacy Rule at 45 CFR 164.512(i) defines the requirements entities must fulfill to use protected health information for research. This includes requirements that the research must be conducted under review of an Institutional Review Board (IRB) or a privacy board with members of varying backgrounds and appropriate professional competency.

For the IRB or privacy board to approve a waiver of individual authorization, researchers must show that the use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals and include an adequate plan to protect the identifiers from improper use and disclosure, an adequate plan to destroy the identifiers at the earliest opportunity, and consistent and adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity. We further note that the research provision (§ 2.52(b)) already includes a requirement that the researcher receiving the part 2 data is fully bound by 42 CFR part 2. We are interested in affording patients protected by 42 CFR part 2 the same opportunity to benefit from research, including research conducted by non-covered entities, while continuing to safeguard their privacy.

Public Comments

One commenter recommended that SAMHSA develop FAQs or guidance to ensure that entities that are not HIPAA-covered entities under HIPAA but who are making disclosures in accordance with the HIPAA Privacy Rule understand their obligations and responsibilities.

SAMHSA Response

We thank the commenter for their suggestion. We note that at the time of the publication of the proposed rule, we published a Fact Sheet, providing a general overview of the proposed rule, available here: <https://www.hhs.gov/about/news/2019/08/22/hhs-42-cfr-part-2-proposed-rule-fact-sheet.html>. We will consider updating subregulatory guidance, as applicable, to include any revisions made in the Final Rule. We will also consider issuing additional subregulatory guidance, as necessary.

Public Comments

One commenter recommended that SAMHSA clarify how the part 2 EHR system should identify characteristics to whom data is sent to including entities that receive data for research purposes. The commenter recommended referencing standards that support conveying these characteristics.

SAMHSA Response

We appreciate the commenter's recommendations. We will evaluate the commenter's suggestions and will consider options to provide technical guidance, including working with ONC and other stakeholders.

Public Comments

One commenter noted that the provisions which facilitate the release of data for research purposes do not necessarily permit disclosure for public health analysis and may not satisfy the requirements of the research exemption. A few commenters recommended including a provision that would explicitly allow the release of data to a state or state data repository if the state agency is authorized by state law to collect such information for the purpose of public health research.

SAMHSA Response

Under our revisions, a part 2 program or other lawful holder of part 2 data is authorized to disclose part 2 data for research purposes, including to state agencies, provided that the disclosure is made in accordance with the HIPAA Privacy Rule requirements at 45 CFR 164.512(i). Broadening the research exception further is beyond the scope of the current rulemaking activities. Note, however, that the CARES Act specifically permits disclosures of de-identified data to a public health authority whether or not a patient gives written consent. HHS anticipates future rulemaking to implement § 3221 of the CARES Act.

Public Comments

One commenter recommended that SAMHSA require that data released should be de-identified and that SAMHSA should define a rigorous process for de-identification.

SAMHSA Response

We encourage 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 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. The proposed changes will require that data is disclosed in accordance with the HIPAA Privacy Rule at 45 CFR 164.512(i), such that researchers from covered entities and non-covered entities, must show that “the research could not practicably be conducted without access to and use of the protected health information.” Compliance with HIPAA and the Common Rule (e.g., IRB and/or privacy board review), as required under existing regulations and the proposed changes to § 2.52, provide sufficient assurances of patient confidentiality, including that the researcher has a plan to protect and destroy identifiers and to

not re-disclose the information in an unauthorized manner.

Public Comments

One commenter recommended that SAMHSA modify the proposal to address the rare situation when the holder of the part 2 data is not subject to HIPAA.

SAMHSA Response

We appreciate the commenter’s suggestion. The revised research exception will permit disclosures of part 2 data for research purposes if 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. Because we are expanding the authority of research disclosures beyond HIPAA-covered entities or entities covered by the Common Rule, we believe it is necessary to ensure that those disclosing the data are familiar with the HIPAA Privacy Rule and the requirements included in the regulations. We agree with the commenter that it will likely be a rare situation when the holder of the part 2 data is not subject to HIPAA and we do not anticipate that it will hinder most research efforts. However, we will consider it for any potential future rulemaking.

Public Comments

One commenter recommended that SAMHSA more closely align with HIPAA and suggested removing language that directs an “individual designated as director or managing director, or individual otherwise vested with authority to act as chief executive officer or their designee” to make a determination regarding the permissibility of research disclosures.

SAMHSA Response

We thank the commenter for the suggestion. Revising the language in this section is beyond the scope of the current rulemaking activities; however, we will evaluate the commenter’s suggestion and consider potential options including future rulemaking.

Public Comments

One commenter noted that the proposed change exceeds the language or the purpose of the enabling statute.

SAMHSA Response

Under 42 U.S.C. 290dd–2(b)(2)(B), the content of an SUD treatment record may be disclosed without patient consent to qualified personnel for the purpose of conducting scientific research provided that such personnel does not identify,

directly or indirectly, any individual patient in any report of such research; thus, we believe that this change does not violate the language of the enabling statute.

Public Comments

Several commenters opposed the proposal to permit research disclosures to members of the workforce of a HIPAA-covered entity for purposes of employer-sponsored research. The commenters noted that the proposal may lead to employment discrimination for those with SUD if data is released for purposes of employer-sponsored research. One commenter noted that it is unclear what “employer-sponsored” research would include.

SAMHSA Response

We proposed to allow part 2 data to be disclosed for research purposes to a member of the workforce of a HIPAA-covered entity. The proposal would clarify that the lawful holder of part 2 data may disclose the data to a member of the workforce of a HIPAA-covered entity provided that the research is being conducted at the direction or on behalf of that individual’s employer. The proposed revisions would only permit this disclosure when the employer requires that all research conducted at the direction or on behalf of the employer is conducted in accordance with the HIPAA Privacy Rule or the Common Rule. During the review of comments, we noted that a few commenters misinterpreted “employer-sponsored research” to include research conducted by employers on or about their employees. It was not our intent to permit employers to conduct SUD research on their employees. Given the concerns and the confusion regarding the proposed changes, we are not finalizing this policy at this time. To reflect this in this final rule, the regulation text proposed at § 2.52(a)(1)(iii) is not being finalized and the regulation text proposed at §§ 2.52(a)(1)(iv) and (v) are being redesignated as §§ 2.52(a)(1)(iii) and (iv), respectively.

Public Comments

A few commenters supported the proposal to permit disclosures 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.

SAMHSA Response

We thank commenters for their support. While we are not finalizing the policy at this time, research disclosures of part 2 data may still be made following the requirements at § 2.52(a).

Public Comments

A few commenters supported the proposal to permit research disclosures to recipients who are covered by FDA regulations for the protection of human subjects in clinical investigations.

SAMHSA Response

We thank commenters for their support.

Public Comments

A few commenters opposed the proposal to permit research disclosures to recipients who are covered by FDA regulations. One commenter stated that a patient's informed consent should be sought when disclosing information for research.

SAMHSA Response

The proposed changes will help align research disclosure requirements among other federal regulations. Allowing research disclosures to recipients who are covered by FDA regulations for the protection of human subjects will help facilitate critical research on SUD treatment and care. We believe it is necessary to strike a balance of promoting research while maintaining confidentiality for patient records. Like the HIPAA Privacy Rule, the FDA regulatory requirements generally require informed consent, except in limited circumstances as explained in 21 CFR part 50. The proposed changes require that the research is in compliance with the requirements of the FDA regulations, including review by an IRB when applicable.

K. Audit and Evaluation (§ 2.53)

In response to comments received, SAMHSA, in § 2.53(c)(1), is removing the expectation that certain audits and evaluations conducted by government agencies and third-party payers would only be conducted periodically, and is making changes to the language in (c)(1)(i)–(iii) to clarify SAMHSA's intent that revisions are intended to help enhance patient care and coverage. SAMHSA is also making several non-substantive changes to the proposed regulatory text of § 2.53, such as updating cross references to other sections of the rule and re-wording and moving the placement of language related to audits conducted by entities that have direct administrative control over a part 2 program.

SAMHSA is finalizing the proposal to permit disclosure of patient identifying information to federal, state, or local government agencies, and to their contractors, subcontractors, and legal representatives for audit and evaluations required by statute or regulation.

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 certain types of reviews. 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) through (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 proposed to make the following changes to the regulations to improve clarity about what is permissible under these sections. SAMHSA also proposed to update part 2 regulatory language related to quality improvement organizations (QIO) to align with 42 CFR 476.1. Specifically, we proposed to replace references to "utilization or quality control review" with the term "QIO review," which is defined in 42 CFR 476.1 as a review performed in fulfillment of a contract with CMS, either by the QIO or its subcontractors.

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 information 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, we stated in the proposed rule that we believe that the concept of audit or evaluation is not restricted to reviews that examine individual part 2 program performance. We specifically said 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, we noted

that 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 programs. 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 proposed 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 stated in the proposed rule that it did not believe it was generally necessary to conduct these types of audits or evaluations on a routine or ongoing basis. Rather, we stated that 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. We also stated that 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). In the 2019 proposed rule, SAMHSA emphasized 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 proposed several changes to § 2.53. First, SAMHSA proposed 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) specified 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 was intended to 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 noted in the proposed rule (84 FR 44579) that it 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, we stated that 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 proposed 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 were also referred to § 2.33, which allows disclosure of information for payment and/or health care operations activities with a patient's consent.

Third, we explained that 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 Conditions 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.

As we noted in the proposed rule (84 FR 44580), 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 proposed to expand the regulatory language to explicitly clarify that this type of information sharing is permitted under the regulations. Specifically, we proposed 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 proposed to include similar language in new subsection (b)(2)(iii). We stated that we believed 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, 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 proposed 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, at the time the NPRM was published, SAMHSA understood 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 and 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 proposed 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 proposed to update language related to quality improvement organizations. At § 2.53(a)(1)(ii) and (b)(2)(ii), it proposed to amend the language to align it with 42 CFR 476.1. Specifically, SAMHSA proposed to replace references to "utilization or quality control review" with the term "QIO review."

The comments we received on the proposed amendments to § 2.53 and our responses are provided below.

Public Comments About the Proposals for Audit and Evaluation in General Public Comments

Several commenters expressed support for the audit and evaluation proposals in general, saying clarification of these provisions can help decrease confusion and administrative burden, particularly among prescribing practitioners and auditors who conduct inspection and evaluation activities. One commenter stated that the proposed changes would enable better evaluation of the entire SUD treatment system of care. Another emphasized that focused oversight will help measure the efficacy of new SUD-related health care benefits offered by government and commercial

programs, reinforcing public trust in such programs while ensuring that adequate funds are available for at-risk populations.

SAMHSA Response

We thank the commenters for their support.

Public Comments

Several commenters were critical of the changes. A few commenters expressed concern about expanded data sharing under the proposals, including with non-government and/or non-treatment actors, that could ultimately negate the current rule's privacy and consent protections.

SAMHSA Response

In this rule, SAMHSA is primarily clarifying activities that are already permissible under § 2.53. Except for new § 2.53(g), we do not interpret the changes as conferring new authority for expanded data sharing and do not believe the changes will undermine the rule's privacy and consent protections.

Public Comments

A few commenters expressed concern that activities under the proposed § 2.53(c)(1)(ii) and/or § 2.53(c)(2) could be used as a means to deny care and/or services to patients with a SUD, and one commenter recommended that SAMHSA provide additional examples of program activities to ensure that such activities are performed in accordance with the regulation. Another commenter said the proposed rule will effectively remove the treating provider from the process.

SAMHSA Response

The goal of our clarifications in § 2.53(c)(1)(ii) and (c)(2) is to ensure that appropriate individuals, agencies and entities may use audits and evaluations to identify opportunities to improve services to patients in part 2 programs, as well as to conduct customary oversight activities that have the ability to safeguard patients and ensure they receive the right care. Without these clarifications, government agencies and third-party payers may be reluctant to undertake certain activities that are important to the care and safety of patients receiving services in part 2 programs. However, as referenced below, SAMHSA is modifying the language at § 2.53(c)(1)(ii) to clarify that the intent of the changes is to enhance care for patients.

Public Comments

A few commenters raised the issue of providing safeguards to prevent release

of individually identifiable information, especially when patient information is used by third parties. One commenter emphasized the importance of ensuring that legitimate contractors use de-identified data whenever possible and follow the part 2 protections.

SAMHSA Response

Section 2.53 includes numerous safeguards to protect patient identifying information. For example, patient identifying information disclosed under § 2.53(a) and (b) may be disclosed only back to the part 2 program or other lawful holder from which it was obtained, and may be used only to carry out an audit or evaluation purpose, or to investigate or prosecute criminal or other activities if authorized by a court order. Under § 2.53(b), individuals, agencies, and entities conducting offsite reviews must maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under § 2.16. Additionally, § 2.13 requires that any disclosures made under the part 2 regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

Public Comments

A few commenters raised the question of how eligible individuals and organizations may access unredacted part 2 information for audits and evaluations under the provisions of the proposed rule, and one stated that the rule does not address the problem of providers who are unwilling to disclose part 2 information to lawful holders subject to state or federal audits, which creates consequences for organizations such as Medicare Advantage Plans. One commenter said there was no process to verify whether identifiable information is needed, emphasizing that patients' private information would be vulnerable to a mere assertion that identifiable information must be revealed. The commenter believes that due process is removed for patients and that the system is ripe for abuse. A commenter suggested that HHS could provide data-use agreements or a memorandum of understanding, or revise the regulation to require a part 2 program or lawful holder to provide part 2 information as necessary to another provider or lawful holder in order to respond to an audit. One commenter suggested that clarification on the specific types of third parties with the specific methods and procedures for obtaining consent would be beneficial.

SAMHSA Response

In this final rule, SAMHSA is clarifying permissible activities under § 2.53 to help clear up confusion about the sharing of patient identifying information for the purposes of audit and evaluation. SAMHSA does not have the statutory authority to require patient records to be disclosed to auditors or evaluators. Further, we decline to issue specific direction regarding the processes through which patient identifying information is disclosed by part 2 programs or lawful holders to auditors and evaluators, as we believe the facts surrounding individual requests for information may vary, and those discussions are better left to stakeholders with first-hand knowledge of each situation. Additionally, SAMHSA believes such questions are out of the scope of this final rule, as they were not addressed in the proposed rule. We will take the suggestion for the creation of data use agreements and/or memorandums of understanding under advisement for future guidance or rulemaking.

Public Comments

A commenter said the correct application of the term "evaluation" is particularly unclear and subject to different interpretations.

SAMHSA Response

As stated in the proposed rule (84 FR 165), 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 would at least include reviews that examine individual part 2 program clinical and/or financial performance as well as reviews of part 2 programs to determine if there are any needed actions at an agency or payer level to improve care and outcomes across individual part 2 programs.

Public Comments

One commenter said that Section 704 of the Comprehensive Addiction and Recovery Act (CARA) of 2016 included provisions permitting Part D sponsors to establish drug management programs (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs and believes that part 2 information will be required to be disclosed. The commenter suggested that SAMHSA include drug management and utilization review programs as program evaluation disclosures that do not require consent for disclosure of part 2 information. Alternatively, the commenter

recommended that the regulations be amended to provide that public program beneficiaries are deemed to have consented to part 2 disclosures when the public program requires such disclosures.

SAMHSA Response

SAMHSA believes it is important to identify patients at risk for misuse or abuse of frequently abused drugs, and that sharing information for the purposes of drug utilization review would already be allowed under §§ 2.31 and 2.33 when a patient consents to sharing their information for payment and health care operations. In this final rule, we are also adopting new language at § 2.53(c)(2) to clarify that audits and evaluations of part 2 programs may include reviews of appropriateness of medical care, medical necessity, and utilization of services. We agree that part 2 programs would be permitted to share information with Part D sponsors seeking to identify at-risk patients who may be candidates for drug utilization programs under this section as well.

Comments on SAMHSA's Proposals To Clarify Permitted Activities of Government Agencies and Third-Party Payers (§ 2.53 (c)(1))

Public Comments

Several commenters expressed support for the proposed changes to clarify the permitted activities of government agencies and third-party payers, stating that they reduce confusion and ambiguity and will help in providing efficient and effective care. A few commenters appreciated the recognition in the proposed rule that state agencies have audit and evaluation responsibilities that necessitate the receipt of part 2-protected data. One commenter underscored that states have an urgent need to utilize every available analytic tool to address the opioid crisis facing our nation.

SAMHSA Response

We thank the commenters for their support.

Public Comments

Several commenters opposed the changes, expressing concerns about expanded sharing of highly sensitive information without patient consent and with few or no parameters, and stating that the audit and evaluation exception already provides a fairly comprehensive mechanism for entities to share information without the consent of the patient. A few believed the changes would permit greater disclosures of patient records without consent to entities not involved in direct patient

care. One commenter said that the proposed rule does not describe how granular level information would be shared between agencies or with third-party payer entities in ways that would not disclose patient identities in any manner and still be useful. One commenter expressed concern that virtually every use will be deemed compelling. A few commenters said that the proposed language exceeds the part 2 statute and that there is no value in maintaining the existing rule without enforcement of it. A few commenters also expressed concern that the proposed changes would allow patient identifying information to be used to reduce care, dictate care, remove the treating provider from the care process, limit access, or make decisions about patient care solely on what can be found in the files through such reviews. Another commenter said that patient records can be inaccurate and are rarely a full reflection of who the person is or the myriad of factors that go into the care process. One commenter said that the proposal opens patients up for discrimination.

SAMHSA Response

As noted in the proposed rule, SAMHSA has heard from stakeholders that there is confusion about what types of activities are permissible under § 2.53. The goal of our clarifications in § 2.53(c)(1) is to ensure that the appropriate individuals, agencies and entities understand that they may use audits and evaluations to identify opportunities to improve services to patients in part 2 programs, including making changes to payment policies that could increase access to effective services and targeting resources more effectively. SAMHSA believes the changes in this section represent clarifications of permissible activities under current regulations. However, in response to concerns expressed above, we are amending the language of this section to help clarify that our intent is to help government agencies and third-party payers as they seek to enhance the care and treatment of patients with SUD. We also note that the regulations include numerous safeguards to help ensure the proper handling of patient identifying information disclosed for audit and evaluation purposes. For example, newly redesignated § 2.53(f) requires that patient identifying information disclosed under this section may be disclosed only back to the part 2 program or other lawful holder from which it was obtained, and may be used only to carry out an audit or evaluation purpose, or to investigate or prosecute criminal or other activities, as

authorized by a court order. Under § 2.53(b), individuals, agencies, and entities conducting offsite reviews must maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under § 2.16. Additionally, § 2.13 requires that any disclosures made under the part 2 regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

Public Comments

One commenter noted that the phrase "across part 2 programs" could be interpreted to mean that evaluations must study only the part 2 programs themselves, and recommended changing this language to "to improve care and outcomes for patients with SUDs that are treated by part 2 programs."

SAMHSA Response

We thank the commenter for this suggestion, and agree that "across part 2 programs" may be interpreted too narrowly. Therefore, in this final rule, SAMHSA has changed the wording in § 2.53(c)(1)(i) to incorporate the commenter's suggested language.

Public Comments

One commenter said the ongoing nature of some Medicaid and Medicaid managed care organization quality control activities may be precluded based on language in the proposed rule stating that these types of audit and evaluation activities should only be periodic in nature. The commenter recommended that SAMHSA remove the "periodic" restriction for entities with direct administrative control and third-party payers, allowing them to continue to be provided with the flexibility to make determinations regarding the appropriate frequency of audit and evaluation activities. Another commenter asked for clarification about allowing "periodic" but not "routine" or "ongoing" reviews, stating that meaningful audits or evaluations that could be appropriately considered "periodic" could also be described as "routine" or "ongoing."

SAMHSA Response

SAMHSA appreciates the insight provided by the commenters. In the proposed rule, SAMHSA sought 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; targeting limited resources more effectively to better care for patients; or adjusting specific Medicaid or other insurance components to facilitate adequate coverage and payment. SAMHSA emphasized in the proposed rule that it did not believe it was generally necessary to conduct these types of audits or evaluations on a routine or ongoing basis. It was not SAMHSA's intention to interrupt or otherwise alter established audit and evaluation programs that already adhere to a specific schedule. Based on the comments received, we do not believe the regulations should indicate the frequency with which the permissible activities outlined in § 2.53(c)(1) should occur. We believe determinations about how often information is disclosed for audits and evaluations of this nature are best left to stakeholders with first-hand knowledge of each specific situation. Therefore, the final regulation text at § 2.53(c)(1) will not include the word "periodically."

Public Comments

One commenter appreciated that SAMHSA believes that the concept of audit or evaluation includes evaluations to identify additional steps and policy changes aimed at improving care and outcomes for part 2 patients, but also supported a broader public health exception to enable part 2 programs to share identifiable information with a public health agency for these purposes. The commenter recommended that § 2.53 be amended to define audit and evaluation as activities to include those conducted by a public health agency authorized by law to conduct public health research and implement programs aimed at improving care and outcomes for part 2 patients.

SAMHSA Response

We thank the commenter for their support and underscore that although the part 2 authorizing statute does not include a broad public health exception to the consent requirements, government agencies that have the authority to regulate, or that financially support part 2 programs, may conduct audits and evaluations of those programs in an effort to ensure that current and future patients receive the best care possible.

Public Comments

One commenter encouraged SAMHSA to include a requirement that any third party acting on behalf of an agency or organization for audits or investigations be required to produce a copy of its contract with the agency or entity on

whose behalf the investigative activities are being conducted, in order to ensure that the third party is legitimate and has the authority to conduct the audit or investigation. The commenter noted that it would be helpful for the entity being audited or investigated to have written assurance that the part 2-covered information can be disclosed and used for these purposes.

SAMHSA Response

We thank the commenter for this suggestion and will consider it for future rulemaking. We underscore the importance for part 2 programs to have processes in place to ensure information is shared appropriately with any contractors, subcontractors or legal representatives conducting audits and evaluations on behalf of the designated individuals, agencies, and entities outlined in § 2.53. SAMHSA encourages part 2 programs and third parties to consider using copies of these types of contracts as one way to help verify a third-party's legitimacy.

In response to comments discussed above, we are finalizing this section with changes. We are removing the word "periodically" from § 2.53(c)(1) and amending the language of § 2.53(c)(1)(ii) and (iii) to help clarify that our intent is to help government agencies and third-party payers as they seek to enhance the care and treatment of patients with SUD. Additionally, we are amending the wording in § 2.53(c)(1)(i) to replace the phrase "across part 2 programs" with the phrase "to improve care and outcomes for patients with SUDs who are treated by part 2 programs."

Public Comments on SAMHSA's Proposal To Clarify Activities Related to Appropriateness of Care, Medical Necessity, and Utilization of Services (§ 2.53(c)(2))

Public Comments

A few commenters supported the proposal, stating that it will support quality improvement and cost containment efforts on the part of third-party payers and resolve ambiguity, and describing it as an essential component that should be retained in final regulations. One commenter stated their understanding that the NPRM is aimed at clarifying which activities fall within the terms "audit and evaluation" and does not necessarily expand or increase the activities already allowed.

SAMHSA Response

We thank the commenters for their support.

Public Comments

Several commenters opposed or expressed concerns about the proposed change. A few commenters said it could jeopardize individual patient insurance coverage, benefits, and access to care; give third-party payers a more defined or interfering role in treatment decisions; and subject patients to criminalization or stigma. One commenter noted they saw no enforcement measures in place to protect patients. Another commenter suggested that the permitted activities could arguably be accomplished through health care operations activities already permitted under § 2.33(b), following patient consent. Other commenters said the proposal exceeded the part 2 authorizing statute and raised concerns about the security of the information, believing that somehow the information would become available to fraudulent individuals marketing the latest SUD miracle cure to patients and families. One commenter said that care coordination should be added to the list of permitted audit and evaluation activities which would involve communication for similar, if not even more beneficial, purposes.

SAMHSA Response

In this rule, SAMHSA is primarily clarifying activities that are already permissible under § 2.53. As stated in the proposed rule, SAMHSA believes the definition of audit and evaluation should and does include reviews to assess 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. With regard to security concerns, § 2.53 includes numerous safeguards to protect patient identifying information disclosed under § 2.53(c)(2). Section 2.53(b), for example, requires auditors and evaluators conducting reviews using information that has been copied, removed, downloaded or forwarded, to maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under § 2.16. Under newly designated § 2.53(f), patient identifying information disclosed under this section may be disclosed only back to the part 2 program or other lawful holder from which it was obtained, and may be used only to carry out an audit or evaluation purpose, or to investigate or prosecute criminal or other activities if authorized by a court order. Additionally, § 2.13 requires that any disclosures made

under the part 2 regulations must be limited to that information which is necessary to carry out the purpose of the disclosure. We note that care coordination is addressed in other parts of this rule.

For the reasons stated above, we are finalizing these changes as proposed.

Public Comments on SAMHSA's Proposal Related to Entities With Direct Administrative Control of Part 2 Programs (§ 2.53(a)(iii) and (b)(iii))

Public Comments

A few commenters supported the proposed change. One commenter described the change as a welcomed clarification.

SAMHSA Responses

We thank the commenters for their support. SAMHSA is finalizing this proposal with minor changes. Specifically, SAMHSA is altering the placement and wording of the new language at § 2.53(a) to better align it with new language at § 2.53(b).

Public Comments on SAMHSA's Proposal Related to Entities That Provide Quality Assurance (§ 2.53(d))

Public Comments

One commenter appreciated the clarification of accrediting organizations (AOs) as entities conducting audits and evaluations under part 2, stating that it is critical for AOs to review part 2 records to ensure that OTPs are meeting certain quality and safety standards in the delivery of care to SUD patients.

SAMHSA Responses

We thank the commenter for their support. We are finalizing this change as proposed.

Public Comments on SAMHSA's Proposal Related to Audits and Evaluations Mandated by Statute or Regulation (§ 2.53(g))

Public Comments

A few commenters appreciated and supported these clarifications and encouraged SAMHSA to finalize them. One commenter suggested that the rules should be revised to apply this exception not just for audits and evaluations required by law, but for any mandated reporting or disclosure required by law.

SAMHSA Response

We thank the commenter for their support. While the part 2 authorizing statute includes an exception to the consent requirement for the purposes of conducting management and financial audits and program evaluations, it does

not include such an exception for any type of mandated reporting or disclosure.

Public Comments

One commenter said the proposed rule change exceeds the authority in 42 U.S.C. 290dd-2 and should be removed. Another commenter expressed concern that the section would act as a catch-all for government agencies and their contractors, subcontractors, and legal representatives to have access to any information that they determine necessary if the state statute mandates the disclosure. The commenter believed this would give the government access to any information that it deems necessary, including managed care companies working as government contractors delivering care to state members. The commenter described the proposal as inconsistent with other portions of the regulations, without providing any specific details, and suggested that SAMHSA should further review the potential implications of this section.

SAMHSA Response

The audit and evaluation exception codified at 42 U.S.C. 290dd-2(B) permits disclosure for a wide range of audit and evaluation activities. We believe that the proposal to permit audit and evaluation by government agencies that are mandated by law is consistent with the authorizing statute and current § 2.53(a) and (b). Furthermore, redesignated § 2.53(f) reiterates that patient identifying information may only be used to carry out the purpose of the audit and evaluation. Moreover, § 2.13(a) prohibits the disclosure or use of patient identifying information in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority. Therefore, we are finalizing § 2.53(g) as proposed.

Public Comments on SAMHSA's Proposal Related To Updating QIO Language

Public Comments

One commenter supported SAMHSA's proposed rule change to align part 2 with current QIO regulations.

SAMHSA Response

We thank the commenter for their support, and we are finalizing our amendments to § 2.53 relating to QIOs as proposed.

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

SAMHSA is finalizing this section as proposed.

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 U.S.C. 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 proposed to amend § 2.67(d)(2), to extend the period for court-ordered placement of an undercover agent or informant to 12 months, while authorizing courts to further extend a period of placement through a new court order (84 FR 55481).

In addition, DOJ has stated that the current regulation text is ambiguous regarding when the current 6-month, or, as finalized, 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 or informant. 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 or informant, for many reasons. Therefore, starting the time period when the court order is issued could significantly curtail the length of time an agent or informant can be undercover at a part 2 program. Furthermore, starting the time period based on date of placement of the agent or informant 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 or informant is aware of the date his or her placement began, but may not be aware of the date of the court order. Thus, SAMHSA proposed to amend § 2.67(d)(2), to clarify that the proposed 12-month time period starts when an undercover agent or informant is placed in the part 2 program (84 FR 55481).

The comments we received on the proposed amendments to § 2.67 and our responses are provided below.

Public Comments

Some commenters opposed the presence of undercover officers and informants in part 2 programs for any length of time, citing privacy concerns, treatment deterrence, ethical violations, and a violation of constitutional rights.

Some commenters specifically stated this proposal would perpetuate stigma. One commenter noted that officers should not be allowed in part 2 programs without proper behavioral health training.

SAMHSA Response

The authorizing statute (42 U.S.C. 290dd–2) and the regulations promulgated thereunder (42 CFR part 2) contain various safeguards to ensure that court orders authorizing the use of undercover agents and informants are not misused. For example, there must be an application citing certain good cause criteria, a court order noting the good cause, and notice provided to the director of the program. Furthermore, no information obtained by an undercover agent or informant placed in a part 2 program under the court order may be used to investigate or prosecute any patient in connection with a criminal matter (42 CFR 2.67(d)). Thus, we believe the regulations strike the appropriate balance between protecting patients from criminal activities by employees of part 2 programs and safeguarding the confidentiality and rights of these same patients.

Public Comments

A few commenters noted that this proposal is particularly concerning given the simultaneous proposal by SAMHSA (at 84 FR 44568) to remove “allegedly committed by the patient” from § 2.63 of the regulations. These commenters argued that, coupled together, the changes would allow the regulations to become a tool of prosecution and not recovery.

SAMHSA Response

As noted above, the authorizing statute (42 U.S.C. 290dd–2) and the regulations promulgated thereunder (42 CFR part 2) contain various safeguards against misuse of these provisions. Further, § 2.13(a) of the regulations specifically provide that “[t]he patient records subject to the regulations in this part may be disclosed or used only as permitted by the regulations in this part and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority. Any disclosure made under the regulations in this part must be limited to that information which is necessary to carry out the purpose of the disclosure.” Thus, we believe that these changes will serve to protect patients from crimes committed in part 2 programs while still safeguarding their confidentiality.

Public Comments

Many commenters disagreed with extending the length of placement of a court-order for an undercover agent or informant from 6 to 12 months, stating that this proposal does not purport to improve care coordination or patient safety. These commenters believe that this proposal may be interpreted by patients and providers as evidence that they are not safe in SUD treatment and may further deter treatment, stating that, given the current nationwide opioid crisis, it is important that SAMHSA strike an appropriate balance and promote greater access to comprehensive and coordinated SUD treatment. Commenters also requested additional details or examples regarding why 12 months is necessary for placement, arguing that there is no evidence that the current policy is encumbering ongoing investigations of part 2 programs or that allowing undercover agents in part 2 programs would address the causes of the opioid crisis. Some commenters noted that this proposal is particularly harmful to individuals living in areas that are already heavily policed.

SAMHSA Response

We disagree that this proposal does not improve patient safety. As noted above, the intent of the regulations is to protect patients, and the regulations at § 2.13(a) provide safeguards to ensure that “[t]he patient records subject to the regulations in this part may be disclosed or used only as permitted by the regulations in this part and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority.” In some situations, in order to build a case of wrong-doing in a part 2 program or by an employee in such a program, evidence must be collected for more than 6 months. We believe that 12 months appropriately strikes a balance between ensuring the necessary time for informants and safeguarding the confidentiality of patients.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are generally required to provide a 30-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. 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. We solicited public comment in the proposed rule on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements (84 FR 44581 through 44584).

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 sought, and considered, public comment on our assumptions as they relate to the PRA requirements summarized in this section.

This final 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 finalized proposal and whether each includes changes to information collection requirements.

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

In section IV.C. of this final rule, SAMHSA is finalizing amendments to § 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 IV.C. for further information about this finalized proposal. As stated in that section, SAMHSA is finalizing

new regulatory text to clarify existing policies; thus, SAMHSA is not finalizing any changes to 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 finalized proposal will 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 finalized proposal results in any changes in collection of information requirements.

In section IV.D. of this final rule, SAMHSA is finalizing amendments to § 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 IV.D. for further information about this finalized proposal. This finalized 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 finalized 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 finalized proposals in sections IV.J., and IV.K, below. This amendment is also anticipated to decrease burden on patients by removing barriers to sharing their own information in order to receive benefits, services, or treatment, but we do not have the data to quantify this reduction.

In section IV.E. of this final rule, SAMHSA is finalizing modifications to 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 IV.E. for further information about this finalized 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 finalized modification of the language results in any changes in collection of information requirements.

In section IV.F. of this final rule, SAMHSA is finalizing with modification its proposal to specify in regulatory text an illustrative list of 17 permitted activities for the purpose of disclosures under § 2.33. SAMHSA is modifying the list of permitted activities to add to § 2.33 that disclosures for care coordination and case management, and disclosures for other payment and/or health care operations activities not expressly prohibited under this provision, are also permitted. See section IV.F. for further information about this finalized proposal. As noted in that section, SAMHSA has previously stated that most of these activities are permitted (83 FR 241); this language will only further clarify the previously finalized policy. Moreover with regard to the addition of care coordination and case management activities to § 2.33, SAMHSA does not believe that this finalized modification of the language will result in providers seeking additional consents to disclosure in the future, nor in any additional burden for providers with regard to documenting consents. Therefore, SAMHSA does not believe this finalized proposal results in any changes in collection of information requirements.

In section IV.G. of this final rule, SAMHSA is finalizing provisions 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 IV.G. for further information about this finalized 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 finalized 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 finalized proposal. Instead, SAMHSA requested that central registries and providers that would query central registries provide comments on any additional

information collection requirements this finalized proposal would cause and any resulting burden. SAMHSA did not receive any comments that would improve estimates of this burden. However, this provision removes barriers and expands eligibility, without requiring non-OTP providers to query the central registry.

In section IV.H. of this final rule, SAMHSA is finalizing its proposal 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 finalized proposal. SAMHSA anticipates that this finalized 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 finalized 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 finalized 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.”¹⁷ 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.¹⁸ 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 × 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 \$24.01¹⁹ per hour for substance abuse, behavioral disorder, and mental health counselors (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 \$851,498 (531,965 clients × 2 minutes (0.033 hours) per access/update × \$48.02/hour) and an annual burden in each year of \$3,405,992 (531,965 clients × 0.133 hours × \$48.02/hour). Therefore, we estimate that this finalized proposal will result in an additional cost of \$4,085,489 (\$851,498 + \$3,405,992), as reflected in Table 1, below.

In section IV.I. of this final rule, SAMHSA is finalizing an addition to § 2.51 to allow disclosure of patient information during natural and major disasters. See section IV.I. for further information about this finalized proposal. Because this finalized proposal by its very nature does not require additional consent requirements or other paperwork, SAMHSA does not believe it will 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 IV.J., and section IV.K. of this final rule, SAMHSA is finalizing changes with modifications to amend §§ 2.52 and 2.53 to allow or clarify the ability to make certain disclosures without patient consent. First, in section IV.J. of this final rule, SAMHSA is finalizing 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 HIPA-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 IV.J. for further information about this finalized proposal. Second, SAMHSA is clarifying 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 identify needed actions to improve the delivery of care, to manage resources effectively to care for patients, and/or to determine the need for adjustments to payment policies to enhance care or coverage for patients with SUD. SAMHSA is also finalizing 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 is finalizing the proposal under § 2.53(g) 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 finalizing updates to language related to QIOs. See section IV.K. for further information about these finalized 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

¹⁸ <https://www.pdmpassist.org/pdf/Resources/Use%20of%20PDMP%20data%20by%20opioid%20treatment%20programs.pdf>.

¹⁹ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment Statistics, May 2019, Substance Abuse, Behavioral Disorder, and Mental Health Counselors, Standard Occupations Classification code (21–1018) [www.bls.gov/oes/current/oes_nat.htm].

¹⁷ <https://www.dasis.samhsa.gov/webt/information.htm>.

and similar organizations. Therefore, although SAMHSA is finalizing language to clarify any confusion that may exist, it believes that these activities are already permitted and that they will not, therefore, result in any new collection of information requirements or any other burden. It also believes updating the QIO language will not create new collection of information requirements or increase burden. As noted above, SAMHSA is also finalizing a provision to clarify that patient identifying information may be disclosed to government agencies and third-party payers to identify needed actions at the agency or payer level, although we are removing the expectation that these reviews would take place periodically due to ambiguity about that term and to avoid interfering with currently-established audit schedules. We are not revising our burden estimates as a result of this modification because the frequency of these reviews is unaffected by the change. Additionally, SAMHSA is adopting a new provision to allow patient identifying information to be shared with 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 IV.D of this final rule, SAMHSA is also finalizing a proposal to allow disclosure to entities with patient consent. SAMHSA believes that the finalized proposals in sections IV.D., J, and K, 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. 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 an average of 15 percent of these records (248,810) as a result of these finalized proposals. We then estimated that 10 percent or 24,881 (248,810 × 10%) of impacted records would be held by part 2 programs who would use paper records to comply with these requests for disclosure reports while the remaining 90% or 223,929 (248,810 × 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 \$22.40.²⁰ 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 \$44.80. 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 \$179.20 (4 hours × \$44.80/hour) and 0.25 hours, on average, to produce information from

a health IT system at a cost of \$11.20 (0.25 hours × \$44.80/hour). 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 finalized proposal will result in an additional cost of \$6,966,680 {(24,881 requests × \$179.20 per request) + (223,929 requests × \$11.20 per request)}, as reflected in Table 1, below.

In section IV.L. of this final rule, SAMHSA is finalizing amendments to § 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 is also finalizing changes to explicitly state when the 12- month period begins to run. See section IV.L. for further information about this finalized 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)).²¹

Below, SAMHSA summarizes the estimated cost of the change in collection of information requirements discussed above. Along with publication of this rule, SAMHSA will submit the information collection revisions associated with this rule to the Office of Management and Budget for approval. After receiving a final action, SAMHSA will publish a notice in the **Federal Register** to inform the public.

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 | \$48.02 | \$4,257,491 |
| §§ 2.31, 2.52, 2.53 (Paper Records) | 24,881 | 1 | 24,881 | 4 | 99,524 | 44.80 | 4,458,675 |
| §§ 2.31, 2.52, 2.53 (Health IT Systems) | 223,929 | 1 | 223,929 | 0.25 | 55,982 | 44.80 | 2,508,005 |
| Total | 780,775 | | 2,908,633 | | 244,167 | | 11,224,171 |

²⁰ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment Statistics, May 2019, Medical Dosimetrists, Medical Records Specialists, and Health Technologists and

Technicians, All Other, Standard Occupations Classification code (29–2098) [www.bls.gov/oes/current/oes_nat.html].

²¹ Except, for this latter case, in the rare circumstance that those information collections are conducted or sponsored by an executive branch department (5 CFR 1320.3(a)).

VI. Regulatory Impact Analysis

A. Statement of Need

This final 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 final 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 finalized policies in this final rule will 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 finalized 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 finalized 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 finalized proposals, SAMHSA was cognizant of privacy concerns and specifically drafted these finalized proposals to protect the privacy of patients; for example, the finalized proposal regarding OTP provider disclosure to PDMPs requires the consent of the patient. SAMHSA believes that increasing patient safety and the empowerment of patients will 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 final 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), 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. We have conducted a regulatory impact analysis for this rule, which we present here.

As discussed in the regulatory impact analysis, we believe this final rule meets the necessary is a de-regulatory action because it eliminates some of the burdens of, and barriers to, SUD treatment record-keeping previously imposed by 42 CFR part 2. The goal of this final rule is to improve the coordination of care for persons with SUD by reducing administrative burdens related to maintenance of disclosures and patient records for downstream, non-part 2 providers. By facilitating care coordination in this way, we anticipate primary care and general medical providers will be more able and more willing to coordinate care for their patients with SUD, and by extension, that quality of care and safety outcomes in the context of the opioids epidemic will improve. This final rule also seeks to facilitate appropriate maintenance of SUD patient records and communications, as by clarifying that

the rule for disclosing SUD treatment records in a “medical emergency” can also apply in natural and major disaster situations. Here again, the goal is de-regulatory, and will reduce the administrative burden for providers in disclosing SUD treatment records in appropriate situations, while also improving care coordination, access to care, and safety during medical emergencies. While we are unable to quantify the benefits related to access and quality of care as well as improved safety and health outcomes for patients with SUD, we believe them to be substantial and to outweigh any additional regulatory burden or economic impacts that may result from the policies finalized in this rule.

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 final rule will 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 finalized 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 V), we estimate the average cost impact per substance abuse treatment admission for staff training, updates to consent forms, and disclosures to agencies will be \$4.32 in year 1 ($\$7,168,135 \div 1,658,732$ patients) and \$4.20 in years 2 through 10 ($\$6,966,680 \div 1,658,732$ patients). For opiate treatment patients, we also estimate the average cost impact for disclosure to PDMPs to be \$8.00 per patient in year 1 ($\$4,257,491 \div 531,965$ patients) and \$6.40 in years 2 through 10 ($\$3,405,992 \div 531,965$ 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 \$12.32 in year 1 and \$10.60 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 final 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 final rule does not have a significant economic impact on a substantial number of small entities.

As further described in section V., 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 finalized 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 finalized proposals in §§ 2.31 and (new) 2.36. In section IV.D. of this final rule, SAMHSA is finalizing its proposal 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 IV.H. of this final rule, SAMHSA is finalizing its proposal 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 IV.D. and IV.H. for further information about these finalized proposals. These finalized 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,²² the reported cost to update authorization forms was \$0.10 per patient. Adjusted for inflation,²³ 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 finalized 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 finalized amendment, we are unable to quantify the reduction in burden related to the expected reduction in the number of required consents.

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 final rule can be accomplished within the existing one hour of training; therefore, we are not finalizing 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.²⁴ 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 \$63.34 per hour for a health specialty teacher²⁵ 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 \$2,407 (19 hours × \$126.68/hour). SAMHSA estimates that the updates to consent forms (§§ 2.31 and 2.36) will be one-time costs the first year the final rule will be in effect and will 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 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.

Public Comments

A few commenters expressed their belief that SAMHSA has underestimated the associated training time required for staff to achieve proficiency with the proposed policies. However, these commenters did not suggest a specific alternative estimate.

SAMHSA Response

We believe that the finalized policies do not substantively add requirements for counseling staff, but are instead modifications, revisions, and clarifications to existing requirements. Therefore, we believe the previously approved estimate of one hour is still appropriate and are not making any updates as a result of the comments received.

In section III.L. of this final rule, SAMHSA is finalizing amendments to § 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 is also finalizing changes to explicitly state when the 12-month period begins to run. See section III.L. for further information about this finalized proposal. Since the requirements for seeking this court order will be the same, and the finalized proposal will merely be extending the time of the court order, SAMHSA does not believe this finalized proposal results in any additional regulatory burden.

Based on the above, SAMHSA estimates in the first year that the final rule will be in effect, the costs associated with the finalized updates to 42 CFR part 2 will be \$11,425,625 as shown in Table 2. In years 2 through 10, SAMHSA estimates that costs will be \$10,372,672. Over the 10-year period of 2020–2029, the total undiscounted cost of the finalized changes will be \$104,779,677 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 \$89.5 million or \$73.8 million, respectively. These costs are presented in the tables below.

²² 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.

²³ <https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-201905.pdf>.

²⁴ <https://www.td.org/insights/how-long-does-it-take-to-develop-one-hour-of-training-updated-for-2017>.

²⁵ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment Statistics, May 2019, Health Specialty Teachers, Postsecondary, Standard Occupations Classification code (25–1071) [www.bls.gov/oes/current/oes_nat.htm].

TABLE 2—TOTAL COST OF 42 CFR PART 2 REVISIONS

| Year | Disclosure to PDMPs | Staff training costs | Updates to consent forms | Disclosures to agencies | Total costs |
|-------|---------------------|----------------------|--------------------------|-------------------------|--------------|
| 2020 | \$4,257,491 | \$2,407 | \$199,048 | \$6,966,680 | \$11,425,625 |
| 2021 | 3,405,992 | 0 | 0 | 6,966,680 | 10,372,672 |
| 2022 | 3,405,992 | 0 | 0 | 6,966,680 | 10,372,672 |
| 2023 | 3,405,992 | 0 | 0 | 6,966,680 | 10,372,672 |
| 2024 | 3,405,992 | 0 | 0 | 6,966,680 | 10,372,672 |
| 2025 | 3,405,992 | 0 | 0 | 6,966,680 | 10,372,672 |
| 2026 | 3,405,992 | 0 | 0 | 6,966,680 | 10,372,672 |
| 2027 | 3,405,992 | 0 | 0 | 6,966,680 | 10,372,672 |
| 2028 | 3,405,992 | 0 | 0 | 6,966,680 | 10,372,672 |
| 2029 | 3,405,992 | 0 | 0 | 6,966,680 | 10,372,672 |
| Total | 34,911,423 | 2,407 | 199,048 | 69,666,800 | 104,779,677 |

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 |
|-------|--------------|--------------------------------|--------------------------------|
| 2020 | \$11,425,625 | \$11,092,840 | \$10,678,154 |
| 2021 | 10,372,672 | 9,777,239 | 9,059,894 |
| 2022 | 10,372,672 | 9,492,465 | 8,467,190 |
| 2023 | 10,372,672 | 9,215,985 | 7,913,262 |
| 2024 | 10,372,672 | 8,947,558 | 7,395,572 |
| 2025 | 10,372,672 | 8,686,950 | 6,911,750 |
| 2026 | 10,372,672 | 8,433,932 | 6,459,579 |
| 2027 | 10,372,672 | 8,188,283 | 6,036,990 |
| 2028 | 10,372,672 | 7,949,790 | 5,642,047 |
| 2029 | 10,372,672 | 7,718,242 | 5,272,941 |
| Total | 104,779,677 | 89,503,284 | 73,837,379 |

We estimated the total annual cost of this rule to be \$10,372,672, ignoring initial transition costs (such as training in the first year). In the Paperwork Reduction Act section, we also estimated that the number of clients treated annually by a Part 2 program to be 1,658,732. Thus, the cost and benefits would break even if the average benefit were \$6.25 per year per client (even if the benefit accrued to providers or others, rather than directly the client). Based on public comments received from affected providers, organizations and entities that this rule will be burden reducing, a deregulatory description seems reasonable. In addition, we note that the estimated costs of this rule come after the first year from disclosure to PDMPs and new disclosures to agencies. However, this rule removes regulatory barriers to those disclosures. It does not require those disclosures.

Because disclosure to PDMPs is permitted, but not required, by this rule, we assume that such disclosures will only be made when providers (and/or states) have decided that the benefits of that disclosure outweigh the costs. Similarly, this final rule permits new disclosures to agencies, including for audit or research purposes, but does not

itself require them. As described above, the rule contains other deregulatory provisions that we have not quantified, such as treatment records from non-Part 2 providers not being covered by Part 2, clarifying sanitation procedures, reducing restrictions on disclosure to organizations with patient consent, and reducing burden/barriers in emergency situations and for research. Thus, this rule is an Executive Order 13771 deregulatory action.

C. Alternatives Considered

In drafting this final rule, SAMHSA considered potential policy alternatives and, when possible, finalized the least burdensome alternatives. For example, in section IV.C. of this final rule, we considered finalizing, specifically, 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 IV.D. of this final 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 finalize 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 finalized proposals in this rule most appropriately balance the often-competing interests of burden, privacy, and patient safety.

D. Conclusion

SAMHSA finalized amendments to 42 CFR part 2. With respect to our finalized proposals to revise the regulations, SAMHSA does not believe that the finalized proposals will 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 final rule will 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 final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. In addition, SAMHSA does not believe this final 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 invited 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. Below are the comments we received as well as our responses.

Public Comments

A few commenters expressed their belief that significant Information Technology barriers involving storing, segmenting, and disclosing/exchanging part 2 information exist which may create disincentives to provide SUD-related services or delays in sharing a patient's SUD record. One commenter recommended that SAMHSA issue a Request for Information to solicit input regarding the specific Health Information Technology (HIT) barriers involved and take steps to address those barriers accordingly. Another commenter stated that while the proposed policies would greatly expand options for our existing service delivery model by allowing clinics to store SUD records in their Electronic Health Record (EHR), the additional capital expense related to purchasing and deploying an upgraded EHR would be prohibitive.

SAMHSA Response

We understand the commenters' concerns and acknowledge that Information Technology challenges and expenses related to the policies being finalized in this rule may exist for certain clinics that provide SUD-related services. However, we believe the specific challenges are not applicable to all SUD providers and are highly unique to those who may experience them to the point where estimating the related expenses would require an assessment of each provider's specific HIT implementation. With specific regard to the cost of upgrading EHR systems, we do not believe the finalized policies would require such an investment and leave the decision to do so to the discretion of each clinic. We thank the commenter for their recommendation that a Request for Information soliciting input on specific HIT barriers be issued, and we will take it under consideration in consultation with ONC.

Public Comments

One commenter expressed its concern regarding additional costs to states to operationalize the segregation of data for PDMPs which may require technological assistance from vendors.

SAMHSA Response

We understand the commenter's concerns and acknowledge that additional costs to states to operationalize the segregation of data for PDMPs may exist for certain states. However, we believe the specific costs may vary substantially and are highly unique to each state to the point where estimating the costs would require an assessment of each state and/or PDMP. We are therefore unable to provide an estimate of the costs states may experience related to this finalized policy.

Public Comments

A few commenters stated their concern that because jurisdictions have not consistently developed or adopted context-specific value sets or machine-readable consent and disclosure rules to allow for automated sensitivity tagging, the updated DS4P standards will result in increased documentation burden and difficult workflows due to the requirement to have to manually tag data as sensitive.

SAMHSA Response

SAMHSA shares the commenters' concerns regarding documentation burden and workflow, however the revised part 2 rule does not involve any update to DS4P standards, and does not impose any requirement for providers to use compliant EHR systems. The revised part 2 rule also does not require non-part 2 providers to segregate any records received from a part 2 program. For these reasons, there is no increased burden to providers under this rule associated with DS4P standards. Any future update to DS4P standards, and any hypothetical burden therefrom, is outside the scope of the current rulemaking. If this issue is addressed through future rulemaking, we may revisit these concerns at that time.

In accordance with the provisions of Executive Order 12866, this final rule has been reviewed by the Office of Management and Budget. Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects in 42 CFR Part 2

Alcohol abuse, Alcoholism, Drug abuse, Grant programs—health, Health

records, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR part 2 as follows:

PART 2—CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS

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

Authority: 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. In paragraph (d)(2)(i)(A) by removing the reference “§ 2.31(a)(4)(iii)(A)” and adding in its place the reference “§ 2.31(a)(4)(i)”;
■ c. Adding paragraph (d)(2)(ii); and
■ d. Revising paragraph (e)(3) and paragraph (e)(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 (d)(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 § 2.13 by revising paragraphs (d) introductory text, (d)(2) introductory text, and (d)(3) to read as follows:

§ 2.13 Confidentiality restrictions and safeguards

* * * * *

(d) *List of disclosures.* Upon request, patients who have consented to disclose their patient identifying information using a general designation pursuant to § 2.31(a)(4)(ii)(B) must be provided a list of entities to which their information has been disclosed pursuant to the general designation.

* * * * *

(2) Under this paragraph (d), the entity named on the consent form that discloses information pursuant to a patient's general designation (the entity that serves as an intermediary, as described in § 2.31(a)(4)(ii)(B)) must:

* * * * *

(3) The part 2 program is not responsible for compliance with this paragraph (d); the entity that serves as an intermediary, as described in § 2.31(a)(4)(ii)(B), is responsible for compliance with the requirement.

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

§ 2.31 Consent requirements.

(a) * * *

(4)(i) *General requirement for designating recipients.* 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)).

* * * * *

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

§ 2.32 Prohibition on re-disclosure.

(a) * * *

(1) This record which has been disclosed to you is 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

* * * * *

■ 7. 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 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. 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 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 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;
- (18) Care coordination and/or case management services in support of payment or health care operations; and/or
- (19) Other payment/health care operations activities not expressly prohibited in this provision.

* * * * *

- 8. Amend § 2.34 by—
 - a. Revising paragraph (b);
 - b. Redesignating paragraph (d) as paragraph (e); and
 - c. Adding a new paragraph (d).
- The revision 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.

* * * * *

- 9. Add § 2.36 to subpart C to read as follows:

§ 2.36 Disclosures to prescription drug monitoring programs.

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 to a prescription drug monitoring program under § 2.31 prior to reporting of such information.

- 10. 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 to medical personnel to the extent necessary to:

- (1) Meet a bona fide medical emergency in which the patient’s prior written 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 or federal authority as the result of a natural or major disaster, until such time that the part 2 program resumes operations.

* * * * *

- 11. 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 45 CFR part 46, 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) 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

(iv) 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 (2) of this section apply to the receiving or disclosing party, this section does not apply.

* * * * *

■ 12. Amend § 2.53:

■ a. In paragraph (a) introductory text by removing the reference to “paragraph (d)” and adding in its place “paragraph (f)”;

■ b. By revising paragraph (a)(1)(ii);

■ c. By adding paragraphs (a)(1)(iii);

■ d. In paragraph (b)(1)(iii) by removing the reference to “paragraph (d)” and adding in its place “paragraph (f)”;

■ e. By revising paragraph (b)(2)(ii);

■ f. By adding paragraph (b)(2)(iii)

■ g. By redesignating paragraphs (c) and (d) as paragraphs (e) and (f), respectively;

■ h. By adding new paragraphs (c) and (d);

■ i. In newly redesignated paragraph (e)(1) introductory text, by removing the reference “paragraph (c)” and adding in its place the reference “paragraph (e)”;

■ j. In newly redesignated paragraph (e)(1)(iii), by removing the reference “paragraph (d)” and adding in its place the reference “paragraph (f)”;

■ k. In newly redesignated paragraph (e)(3)(ii)(F), by removing the reference “paragraph (c)(1)” and adding in its place the reference “paragraph (e)(1)”;

■ l. In newly redesignated paragraphs (e)(4) and (5), by removing the reference “paragraph (c)(2)” and adding in its place the reference “paragraph (e)(2)”;

■ m. In newly redesignated paragraph (e)(6), by removing the reference “paragraph (c)” and adding in its place the reference “paragraph (e)”;

■ n. In newly designated paragraph (f), by removing the reference “paragraph

(c)” and adding in its place “paragraph (e)”;

■ o. Adding paragraph (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.

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

(b) * * *

(1) * * *

(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 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 for patients with SUDs who are treated by part 2 programs;

(ii) Ensure that resources are managed effectively to care for patients; or

(iii) Determine the need for adjustments to payment policies to enhance care or coverage for patients with SUD.

(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 deidentified information.

■ 13. 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;

* * * * *

Dated: June 22, 2020.

Elinore F. McCance-Katz,

Assistant Secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration.

Approved: July 1, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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