

Department of Health and Human Services
Office for Civil Rights (OCR) and
the Substance Abuse and Mental Health Services Administration (SAMHSA)
Follow up Report on the
42 CFR Part 2 Tribal Consultation Recommendations
June 2023

Disclaimer

This document is a summary of testimony provided at the Office for Civil Rights (OCR) and Substance Abuse and Mental Health Administration (SAMHSA) Tribal Consultation on proposed changes to 42 CFR Part 2 Confidentiality of Substance Abuse Patient Records. The document itself does not constitute legal advice, has no force or effect of law, and does not create any legally binding rights or obligations binding on persons or entities. This document does not reflect the opinion or position of OCR or SAMHSA; rather, it provides a comprehensive overview of oral and written testimony received during the consultation.

Introduction

The Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) and Office for Civil Rights (OCR) strongly support and respect Tribal sovereignty and self-determination and are committed to working with Federally recognized Tribal governments on a government-to-government basis.

On February 2, 2022, OCR and SAMHSA announced Tribal Consultation on the proposed changes to 42 CFR part 2 (also referred to as “Part 2”) Confidentiality of Substance Use Disorder Patient Records via a Dear Tribal Leader letter and communication with various Tribal partners.

Virtual Consultation was held on March 10, 2022, from 4:00-5:00 pm EST. Written comments were accepted until April 6, 2022. There were 201 registered participants, including Tribal leaders, OCR and SAMHSA senior leaders, other HHS and government staff and other Tribal partners. Six written comments were received.

The Part 2 Confidentiality Consultation provided an opportunity for OCR and SAMHSA to inform Tribes about the Part 2 regulation and changes, receive comments, and answer questions on these topics. In addition, OCR and SAMHSA asked Tribal leaders for input on specific questions related to Part 2. These questions were:

- How does 42 CFR part 2 impact patient care, outcomes and privacy for Tribal Nations and Tribal citizens?
- What specific changes to Part 2, if any, would benefit American Indian and Alaska Native people seeking care and Tribal entities?
- How will the Coronavirus Aid, Relief, and Economic Security (CARES) Act changes to confidentiality requirements affect patient care, outcomes, and privacy for Tribal Nations?
- What additional sub regulatory guidance or technical assistance on Part 2 would be helpful to Tribal entities?
- Are there privacy requirements in Tribal Law that HHS should be aware of that also apply to Part 2 programs?

This report, initially shared in July 2022, provides Tribal leaders with a summary of recommendations and input received during the consultation period and provides responses from OCR and SAMHSA and a brief update on current status as of June 2023.

Background

[Title 42 of the Code of Federal Regulations \(CFR\) Part 2: Confidentiality of Substance Use Disorder Patient Records \(Part 2\)](#) was first promulgated in 1975 to address concerns about the potential use of Substance Use Disorder (SUD) information in non-treatment-based settings such as administrative or criminal hearings related to the patient. Part 2 is intended to ensure that a patient receiving treatment for a SUD in a Part 2 Program does not face adverse consequences in relation to issues such as criminal proceedings and domestic proceedings such as those related to child custody, divorce, or employment. Part 2 protects the confidentiality of SUD patient records by restricting the circumstances under which Part 2 Programs or other lawful holders can disclose such records.

[For more information, fact sheets, and a list of frequently asked questions about Part 42, visit the SAMHSA website.](#)

SAMHSA is working with the HHS Office for Civil Rights on a final rule to implement changes required by section 3221 the CARES Act to the 42 CFR part 2 regulations governing the confidentiality of substance use disorder patient records. We intend to publish these amendments later this year in the *Federal Register*. Until new regulations are finalized, the current 42 CFR part 2 regulations remain in effect.

Recommendations and Responses

Summary of Input

Limiting SUD information impedes providers' ability to provide comprehensive care for people with SUD by limiting access and integration of behavioral health records

It is essential that health care providers have access to the information they need to provide appropriate care.

The recent changes by SAMHSA to Part 2 fell short of facilitating integrated health care. Increasingly, primary care providers, especially in integrated health care systems or underserved or rural areas, are providing addiction treatment in limited circumstances. Primary care providers who, as part of their practice monitor and prescribe buprenorphine or related drugs, have concerns that this part of the record becomes subject to 42 CFR part 2 requirements.

Another challenge for primary care providers is that sequestering a record, or a portion of the record requires specialized programming which increases the cost and complexity of the electronic health record (EHR). Medical EHRs have many important innovations that could benefit patients, but behavioral health patients can miss out on the improvements to care these innovations could provide for their behavioral health care because of the existing regulations.

RECOMMENDATIONS:

- Clarify that primary care providers within integrated team environments are not subject to 42 CFR Part 2 unless the entire treatment program is dedicated to a substance or alcohol addiction treatment. This change would move the primary care community toward greater confidence in treating these patients.

RESPONSE: SAMHSA and OCR will consider these topics for future training or guidance on the application of Part 2. The CARES Act did not amend the definition of a Part 2 program or the applicability provisions of Part 2. A program's records are subject to Part 2 if the program is federally assisted and holds itself out as providing SUD treatment and provides such treatment.

UPDATE: No further update.

- Provide guidance for primary care providers or integrated providers who medically manage people in recovery from substance use.

RESPONSE: SAMHSA and OCR will consider this topic for future guidance on the modified Part 2 requirements once a rule is finalized.

UPDATE: No further update, as the rule is not yet final.

- Part 2 should not limit the ability of all of the patient's treatment providers to access the patient's clinical records, including SUD treatment records.

RESPONSE: Under the Part 2 statute, as amended by the CARES Act, a patient may provide written consent once for all future uses and disclosures of their Part 2 record for treatment, payment, and health care operations. *See* 42 U.S.C. 290dd-2(b)(1).

UPDATE: No further update.

Summary of Input

Support for changes to the current 42 CFR part 2 to reinforce integrated care and coordination between providers and individuals with SUD

Proposed changes would certainly support integrated care and coordination between providers for individuals with SUD. Recognizing, and specifically acknowledging, that records created by a single provider or clinic providing both primary care and monitoring substance use treatment and documents, such as medication lists, are not subject to the heightened 42 CFR part 2 privacy requirements would be a positive step.

RECOMMENDATIONS:

- Allow the ability to share information for care coordination without specific patient consent would support the response to sub-acute crises as they occur.

RESPONSE: The Part 2 statute, as amended by the CARES Act, permits sharing Part 2 records for treatment without specific patient consent, based on a single consent provided once for all future treatment, payment, and health care operations activities.

UPDATE: No further update.

- Transition towards a Health Insurance Portability and Accountability Act (HIPAA)-like standard for information sharing to coordinate services for SUD records.

RESPONSE: The CARES Act created some alignment between Part 2 and the Privacy Rule; however, patient consent generally is still required for Part 2 disclosures for treatment (including care coordination), payment, and health care operations, although consent need only be provided once for all such future activities.

UPDATE: No further update.

- Allow access to SUD records to all treatment providers to improve care and reduce costs associated with sequestering these records.

RESPONSE: The Part 2 statute, as amended by the CARES Act, permits Part 2 programs, covered entities, and business associates that receive Part 2 records under a written consent for all future uses and disclosures for treatment, payment, and health care operations to re-disclose the records as permitted by the Privacy Rule, with a couple of exceptions. *See* 42 U.S.C. 290dd-2(b)(1)(B).

UPDATE: No further update.

- Align Part 2 with other HIPAA privacy requirements, including but not limited to, those requirements for accounting of disclosures, requests for amendments, and requests for restrictions.

RESPONSE: Section 3221 of the CARES Act establishes patient rights to an accounting of certain disclosures of Part 2 records and requests for restrictions of disclosures of Part 2 records for treatment, payment, and health care operations.

UPDATE: No further update.

Summary of Input*Hold ongoing meaningful consultation with Tribal Nations and facilitate Urban Confer sessions for Urban Indian Organizations (UIOs) to ensure that Part 2 compliance is not a barrier to care and SUD services for AI/AN people*

There is a need to also facilitate an Urban Confer session for Urban Indian Organizations (UIOs) on the proposed changes to 42 CFR part 2. Many UIOs provide treatment for substance use and mental health conditions to American Indians and Alaska Natives (AI/ANs) living in urban areas. It is critically important that UIOs are informed of changes to rules which affect the AI/AN health care providers equally and are given the opportunity to provide feedback and input on those changes.

RECOMMENDATIONS:

- Hold ongoing meaningful consultation with Tribal Nations to ensure that Part 2 compliance is not a barrier to care and SUD services for AI/AN people.
- Facilitate an Urban Confer session for Urban Indian Organizations (UIOs) on the proposed changes to 42 CFR part 2

RESPONSE: SAMHSA, in collaboration with OCR, plans to provide a webinar to Urban Tribal Organizations on the Notice of Proposed Rulemaking (NPRM) for Confidentiality of Substance Use Disorder (SUD) Patient Records, 42 CFR part 2, when the NPRM with changes required by the CARES Act, is published in the *Federal Register* and the comment period is open. This will provide an opportunity for SAMHSA and OCR to explain the proposed changes to Part 2, which we cannot discuss currently as they are under deliberation. The information provided in the webinar could help inform any public comment stakeholders would like to provide on the proposals.

UPDATE: SAMHSA and OCR are currently planning to hold a listening session for Urban Indian Organizations in summer 2023.

Summary of Input

Coordination between Federal agencies

The Indian Health Service (IHS) is a unique health system and the primary focus of coordinating care for those within our communities dealing with a SUD. This requires coordination between various supporting agencies and partners.

RECOMMENDATIONS:

- Work with the Indian Health Service (IHS), the Veterans Health Administration and other federal departments or agencies supporting SUD services or funding to better align, leverage, and coordinate federal efforts and resources to effectuate comprehensive SUD services and programs for American Indian and Alaska Native (AI/AN) individuals, families, and communities.

RESPONSE: We acknowledge the importance of working closely with IHS and other federal agencies during this process. **SAMHSA works closely with IHS on the opioid grants funded by each agency and other programs. SAMHSA also works closely across departments on initiatives related to the Tribal Law and Order Act (TLOA). This includes partnerships with the Department of Justice as well as the Department of Interior.**

UPDATE: SAMHSA and OCR continue to work closely and in coordination with multiple federal agencies to ensure efforts and resources are aligned.

Summary of Input

Many Tribal Nations are moving toward Health IT modernization, many of these IT needs will be guided by unique models of care that seek to integrate teams and provider specialties

There are concerns over electronic health records (EHR) and that the current IHS Resource and Patient Management System (RPMS) system does not allow for the segregation of electronic records among providers. Additionally, several participants mentioned that care integration and sharing records are crucial for their facilities and many are concerned that Part 2 may inadvertently slow down the coordination of treatment due to concerns about the confidentiality of certain records.

RECOMMENDATIONS:

- IHS and tribal facilities using RPMS be provided with ongoing training (live and/or electronically accessible) that is made available as to compliance with Part 2 until IHS modernizes its EHR system. This education and training should be maintained during the forthcoming EHR system upgrade to ensure that individuals with SUD are treated fairly and with the maintenance of confidentiality.

RESPONSE: SAMHSA and OCR will discuss this recommendation with IHS.

UPDATE: This recommendation has been shared with IHS, who have the ultimate responsibility for EHRs at IHS facilities.

Summary of Input ***A distinction between integrated care systems and clinics or programs specific SUD treatment should be made***

Individuals receiving care within an integrated system have better outcomes because of the coordinated approach to health care delivery and artificial barriers to this coordination are cumbersome. Patients should have the ability to opt out of information sharing within an integrated care model, but it should not be the default.

RECOMMENDATIONS:

- Sequestration of SUD records could be eliminated, if not for all SUD records, some records. Keeping progress notes segregated from the integrated record could maintain a measure of confidentiality while ensuring providers have the information, they need to provide appropriate care.

RESPONSE: The CARES Act created some alignment between Part 2 and the Privacy Rule; however, patient consent generally is still required for Part 2 disclosures for treatment (including care coordination), payment, and health care operations, although consent need only be provided once for all such future activities.

UPDATE: No further update.

Summary of Input *CARES Act changes to confidentiality requirements impact patient care, outcomes, and privacy for Tribal Nations*

HIPAA Rules require covered entities to seek "authorization" to release treatment and other records while Part 2 requires "consent". "Consent" is closely tied to consent for treatment, not necessarily to the disclosure of patient information. Under the current rule, Part 2 applies even to those that receive Part 2 records with valid consent or authorization. This presents further costs and complexities associated with releasing Part 2 records.

Tribes are concerned with how this will impact overall patient care including the rights of patients and providers, alike. More clarification and guidance are needed for IHS/Tribal facilities and providers to coordinate care effectively and safely. Also, Tribal Nations have varying electronic health record systems and integration with pharmacies.

RECOMMENDATIONS:

- Clarify the difference between consent under Part 2 and authorization under HIPAA to help eliminate confusion between the two terms and align Part 2 with HIPAA's authorization requirements for disclosures.

RESPONSE: SAMHSA and OCR appreciate the recommendation and will consider this topic for future guidance.

UPDATE: This is still being considered for inclusion in future guidance.

- Consider eliminating additional burdens on covered entities.

RESPONSE: SAMHSA and OCR will publish a Regulatory Impact Analysis as part of the proposed rule that addresses, and requests public comment on, burdens and benefits to the regulated community, including HIPAA covered entities that are also Part 2 programs.

UPDATE: SAMHSA and OCR published a Regulatory Impact Analysis addressing, and requesting public comment on, these issues. The final rule will also include a Regulatory Impact Analysis, which will be informed by the public comments received.

- Apply the HIPAA/HITECH breach notification requirements for Part 2 records and it would be preferable to report these matters under the current HIPAA requirements. Meaning a breach under Part 2 would be responded to and reported to the Office for Civil Rights under the HIPAA privacy rule.

RESPONSE: The Part 2 statute, as amended by the CARES Act, requires breach notification by Part 2 programs that experience a breach “to the same extent and in the same manner as such provisions apply to a covered entity in the case of a breach of unsecured protected health information.” 42 U.S.C. 290dd-2(j).

UPDATE: No further update.

- Provide technical guidance on procedures for breach notifications and any related penalties or enforcement. We understand that these should align with sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d–5 and 42 U.S.C. 1320d–6), which are the penalties imposed for HIPAA violations.

RESPONSE: SAMHSA and OCR appreciate the need for guidance, especially for Part 2 programs that are not already subject to breach notification requirements and enforcement penalties because they are not HIPAA covered entities. We anticipate providing education for providers following publication of a final rule.

UPDATE: No further update, as the rule is not yet final.

- Provide clarification on the specific public health purposes that would trigger a Part 2 record to be disclosed for public health purposes, albeit in a de-identified format.

RESPONSE: SAMHSA and OCR appreciate the recommendation and will consider this topic for future guidance.

UPDATE: No further update.

- Expand on the permitted re-disclosures as it relates to pharmacies.

RESPONSE: SAMHSA and OCR appreciate the recommendation and will consider this topic for future guidance.

UPDATE: No further update.

- Provide clarification on any modifications that will trigger changes to its Notice of Privacy Practices (NPP). Simply modifying the NPP under HIPAA to include Part 2 would eliminate additional costs and complexities of having to post two different notices.

RESPONSE: Section 3221 of the CARES Act requires modification of the HIPAA Notice of Privacy Practices to address Part 2 so that a covered entity that is also a Part 2 program would only need to post a single notice.

UPDATE: No further update.

- Health care should be a safe space for a patient to work with their provider toward recovery without fear of reprisal or legal consequences.

RESPONSE: As amended by the CARES Act, the Part 2 statute at 42 U.S.C. 290dd-2(c) prohibits the use of a patient's Part 2 records or testimony relaying the information in the records in civil, criminal, administrative, or legislative proceedings against the patient without a court order or patient consent.

UPDATE: No further update.

- Law enforcement and health care need to remain firmly separated. There should be a prohibition on the use and disclosure of SUD records in civil, criminal, administrative, and legislative proceedings by a federal, state, or local authority against a patient, absent a court order or the consent of the patient. Nor should covered entities be required to release information to teams established through a drug court program.

RESPONSE: As amended by the CARES Act, the Part 2 statute at 42 U.S.C. 290dd-2(c) prohibits the use of a patient's Part 2 records or testimony relaying the information in the records in civil, criminal, administrative, or legislative proceedings against the patient without a court order or patient consent.

UPDATE: No further update.

- Civil and criminal penalties should be reserved for the most egregious or malicious violations or breaches and be proportional to the violation or breach.

RESPONSE: Section 3221(f) of the CARES Act, Part 2 provides that violators will be subject to the penalty tiers established by the HITECH Act for HIPAA violations. *See* 43 U.S.C. 1320d-5 and 1320d-6. The penalty tiers reflect levels of culpability for violations. *See* 45 CFR 160.404.

UPDATE: No further update.

Summary of Input*There is confusion on the timeline of Implementation regarding 42 CFR part 2*

SAMHSA's recent actions around Part 2 have created confusion for providers, particularly because the statutory changes laid out in the Coronavirus Aide, Relief, and Economic Security Act (CARES Act) have not been implemented in the last two years since the Act was passed. SAMHSA issued a statement on April 9, 2021, regarding Part 2 (<https://www.samhsa.gov/newsroom/statements/2021/42-cfr-part-2-amendments-process>). In its statement, SAMSHA asserted that it intended to publish amendments to the Part 2 regulations

late 2021, and it affirmed that the current Part 2 regulations (including the July 15, 2020, Final Rule) remain in effect.

Prior to this on March 27, 2020, the CARES Act was signed into law containing a section amending Part 2. SAMHSA published a Final Rule on July 15, 2020, providing clarification on Part 2's requirements for SUD data. This Final Rule was originally proposed before the CARES Act was signed into law, and therefore the Final Rule was not intended to implement or enforce the new CARES Act provisions. This has created confusion for providers and entities receiving Part 2 data as they need to review and evaluate how to address the current inconsistencies between the SAMSHA July 15, 2020, Final Rule and the CARES Act changes amending Part 2.

While awaiting structural changes in a new Final Rule on Part 2, providers need new guidance now to address the conflicts between the existing regulations and the CARES Act statutory requirements.

RECOMMENDATIONS:

- Provide more centralized and comprehensive guidance on interpreting and implementing Part 2, especially as to common questions from providers, similar to the Office for Civil Rights Frequently Asked Questions (FAQs) for Professionals on HIPAA. Many entities rely on the Legal Action Center (LAC) for interpretation and guidance, however, while LAC does a great job, having FAQs from SAMSHA would be more authoritative and accessible.
- Update any FAQs frequently in response to common questions that arise or emerge with new technology. This will be especially important with the Part 2 revisions under the CARES Act since those will be significant changes.

RESPONSE: SAMHSA and OCR appreciate the recommendation. The current regulation, 42 CFR part 2, remains in effect until modified in a final rule published in the *Federal Register*. We will take under advisement the recommendations for improvements to providing guidance on interpreting Part 2. SAMHSA at this time also supports the Center for Excellence on Protected Health Information that can help answer questions from tribal patients and providers (<https://coephi.org/>).

UPDATE: No further update.

Summary of Input

Address existing Public Health Emergency (PHE) Flexibilities

While addressing the conflict between existing Part 2 regulations and the CARES Act statutory requirements is necessary, SAMHSA must also address its standing PHE flexibilities in any new regulations. Current flexibilities provided by SAMHSA allow behavioral health providers working through telehealth the discretion to disclose certain patient identifying information to medical personnel to address a bona fide medical emergency without first obtaining patient

written consent. This recognizes the difficulty of obtaining written consent when patients and providers are not located in the same place, which is particularly acute in rural areas. These types of flexibilities get to the heart of the need for behavioral health providers to work with medical providers and share relevant information currently covered and sequestered by Part 2. When the federal PHE ends, these types of flexibilities will also end.

RECOMMENDATIONS:

- Provide guidance and new regulations addressing these disclosures updated and in place to support continued emergency care for SUD patients.

RESPONSE: SAMHSA and OCR recognize the importance of clear and up to date guidance for care related to SUD. Once the final rule is promulgated, SAMHSA will work with Tribes and IHS to share guidance and relevant information on a timely basis.

UPDATE: No further update, as the rule is not yet final.

Summary of Input

Recognize potential impact on comprehensive health care services

The IHS and tribal facilities offer an array of health care services to AI/AN communities with services varying between facilities. Some facilities offer comprehensive health care services, including mental health and SUD services, and have experience with the implementation of Part 2. With the availability of federal and state opioid funding for tribes to offer SUD and medicated-assisted treatment (MAT) at IHS and tribal facilities, more tribes are concerned or have questions about the applicability of Part 2 consent procedures on IHS and tribal facilities.

Some tribes are also concerned about a patient revoking consent and what that would mean for continuity and coordination of care in the future. The complexity of Part 2 also deters IHS and tribal facilities from implementing SUD/MAT services or may result in a facility not complying with the requirements.

RECOMMENDATIONS:

- Create a Tribal-Specific Decision Tree or Flow Chart on Part 2 application, SAMHSA has issued guidance to help stakeholders understand their rights and obligations under the regulations.
- We request that SAMHSA set up roundtables with tribes, or a workgroup, to develop a Tribal-specific “decision tree” or flowchart model that takes into consideration Tribal models of integrated and/or coordinated care to assist in determining Part 2 application.
- Create an IHS/Tribal Facility Help Desk
- Identify a contact at SAMHSA that can provide technical support to answer questions by IHS/Tribal Facilities and providers.

RESPONSE: SAMHSA and OCR will consider ways to work closely with Tribes in every step of the process. We will also support continued collaboration with IHS to address technical support needs. SAMHSA will also rely on the expertise of the Tribal Technical Advisory Committee (TTAC) to lead and support work on any guidance documents for Tribal models of integrated care. Additionally, SAMHSA at this time also supports the Center for Excellence on Protected Health Information that can help answer questions from tribal patients and providers (<https://coephi.org/>).

UPDATE: SAMHSA and OCR continue to identify areas to work closely with Tribes during this process.

Summary of Input

Clarify that IHS/Tribal Facilities are Not Part 2 Entities Because SUD/MAT Care is Incident to the Providing Health Care

SAMHSA has limited the applicability of 42 CFR part 2 to “programs” that hold themselves out as providing, and which actually provide, alcohol or drug abuse diagnosis, treatment, and referral for treatment. This was intended to lessen the adverse economic impact of the regulations on a substantial number of facilities that provide SUD care only as incident to the provision of general medical care.

SUD/ Medicated-Assisted Treatment (MAT) services at Indian Health Service (IHS) and tribal facilities, are clearly incident to the provision of general medical care particularly when you look at the comprehensive health services that are provided in proportion to any SUD/MAT services that may be offered within IHS and tribal facilities.

However, some IHS and tribal facilities are concerned that by merely letting patients know about the availability of SUD/MAT services at an IHS or tribal facility or advertising the services, these actions could be construed as the IHS or tribal facility “holding themselves out” as a provider of opioid misuse, diagnosis, and treatment services. Making known the availability of MAT services at an IHS or tribal facility to AI/ANs is a key component to getting AI/AN to seek SUD/MAT treatment. Some tribes have seen drastic growth of a MAT program once AI/AN learn about the services at their IHS or tribal facility.

Some IHS and tribal facilities are also concerned overall with how to integrate MAT into their general medical facilities as part of primary care without invoking Part 2 regulations. Apart from the outreach and education issues raised above, there are many specific workflow issues that arise within a general medical facility that is interested.

RECOMMENDATIONS:

- Ensure the rule or guidance specifically state that IHS and tribal facilities are non-Part 2/uncovered entities because they provide SUD/MAT care incident to the provision of general medical care.
- Clarify that any outreach (merely letting patients know, posting notices, advertising, etc.) or education about the availability of MAT services at a general medical care facility, including IHS and tribal facilities, does not change the non-Part 2/uncovered entity status of these facilities.
- Issue guidance that clarifies that any outreach (merely letting patients know, posting notices, advertising, etc.) or education about the availability of MAT services at a general medical care facility, including IHS and tribal facilities, *does not change* the non-Part 2/uncovered entity status of these facilities.

RESPONSE: SAMHSA and OCR will consider ways to clarify the applicability of Part 2 to SUD/MAT treatment within a general medical care facility. The CARES Act did not amend the definition of a Part 2 program or the applicability provisions of Part 2; however, we appreciate that integration of medical and SUD treatment furthers the aims of care coordination. A program's records are subject to Part 2 if the program is federally assisted and holds itself out as providing SUD treatment and provides such treatment. The definition of program includes an identified unit within a general medical facility or specific providers within a general medical facility.¹

UPDATE: No further update.

Summary of Input

Guidance on IHS and Tribal Facilities Offering SUD/MAT Services

RECOMMENDATIONS:

- Provide clear technical guidance to IHS and tribal facilities on the application of 42 CFR part 2 when IHS and tribal facilities offer SUD/MAT services and integration of behavioral healthcare services. This guidance should indicate clear examples of how to navigate the following:
 - Dual-credentialed providers
 - Providing MAT as part of primary care – needing to schedule patients into certain clinic spaces and timeslots with waived providers.

¹¹ See 42 CFR 2.11 Definitions. *Program* means:

(1) An individual or entity (other than a general medical facility) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or

(2) An identified unit within a general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or

(3) Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.

- Internal mechanisms on how IHS and tribal facilities navigate unauthorized access, *or* the possibility of a provider *accidentally* clicking on a record
- How to navigate “open” or “integrated” care team models that encourage team huddles where de-identified SUD appointment information may be shared for care coordination purposes
- How to document prescriptions for MAT in the setting of an integrated pharmacy package within an electronic health record (EHR) system
- Peer support providers for SUD working in a primary care facility

RESPONSE: SAMHSA and OCR acknowledge and appreciate these recommendations for technical assistance topics. We will consider these scenarios as we develop education and training for providers on the new regulations once finalized.

UPDATE: No further update, as the rule is not yet final.

Summary of Input*Other Recommendations Received:*

- Establish an Urban Confer policy to set the necessary policies and procedures for direct and clear communication with UIOs.

RESPONSE: We have proposed providing a webinar to Urban Tribal organizations on the Notice of Proposed Rulemaking (NPRM) for Confidentiality of Substance Use Disorder (SUD) Patient Records, 42 CFR part 2 (Part 2), when the NPRM is published in the *Federal Register* and the comment period is open. This will provide an opportunity for SAMHSA and OCR to explain the specific proposed changes to Part 2, which are currently not finalized.

UPDATE: SAMHSA and OCR are currently planning to hold a listening session for Urban Indian Organizations in summer 2023.

- Remove the two-year requirement for Tribal applicants in the Tribal Opioid Response program funding grants and elsewhere.

RESPONSE: There is no longer a requirement for Tribes to attest that they don’t meet the 2 years of experience to obtain tribal opioid response funding.

UPDATE: No further update.