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HEALTH INFORMATION AND DATA SHARING

Fact Sheet

Understanding and Implementing the Updates to 42 CFR Part 2, Confidentiality of Substance Use Disorder Patient Records.

This resource is not a comprehensive examination of the application of Part 2 to every circumstance and is not legal advice, but rather an informational tool to help practitioners and public health officials gain a deeper understanding of the updates to Part 2. The Network recommends seeking legal counsel or an attorney for legal advice regarding specific situations and the potential applicability of state and local laws.

Introduction

On February 8, 2024, the U.S. Department of Health & Human Services (HHS) through the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office for Civil Rights released a final rule modifying the Confidentiality of Substance Use Disorder (SUD) Patient Records regulations at 42 CFR Part 2 ("Part 2").[1] The effective date of the new rule was April 16, 2024, with entities having until February 16, 2026, to comply with the updates. The updates are significant and will affect the operations of every Part 2 program and provider.

On March 15, 2024, the Network for Public Health Law published a summary of notable changes to the Part 2 Rule. This new resource expands upon that 2024 summary. It first provides a brief background on Part 2 and its application. It then delves into more detail on some key updates with a focus on practical guidance around implementation. Part 2 programs that are also Health Insurance Portability and Accountability Act (HIPAA). covered entities may be well-positioned to comply with the changes that create greater alignment between HIPAA and Part 2. Part 2 programs that are not subject to HIPAA may not be as familiar with some of the updates and will need to allocate adequate time to review and implement the updates prior to 2026.

Part 2 Overview

Individuals with a substance use disorder (SUD) may be particularly vulnerable to discrimination, for example, in housing, employment, and access to services. Part 2 is explicit that its intent is "to ensure that a patient

receiving treatment for a substance use disorder in a Part 2 program is not made more vulnerable by reason of the availability of their record than an individual with a substance use disorder who does not seek treatment."[2] As such, Part 2 applies stringent privacy protections on qualifying Part 2 records.

Part 2 protections only apply only to records from certain programs, often referred to as "Part 2 programs." To qualify as a Part 2 program, an organization or agency must meet the definition of both "program" and "federally assisted."

A "program" is defined in one of three ways.

- It can be either an individual or entity, other than a general medical facility, "who holds itself as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment."[3] For example, this could be a residential SUD treatment facility or private practice medical practitioner specializing in medication assisted treatment (MAT).
- Second, it can be 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."[4] For example, this could be a detox facility that is part of a larger hospital.
- Finally, it can be either 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."[5] An example of this could be a physician or licensed substance disorder counselor at a hospital who specialize in treating substance use disorders.

The definition of "federally assisted" is very broad.[6] A program is "federally assisted" if it receives federal funds, support or authorization. This can include:

- Being conducted in whole or in part by any federal department or agency (with some limited exceptions);
- Being carried out with a license, certification, registration, or other authorization granted by any federal department or agency, including participating providers in the Medicare or Medicaid programs, authorization to conduct maintenance treatment or withdrawal management, or registration to dispense a controlled substance (e.g., holding a DEA license);
- Being supported by federal funds, including financial assistance that does not directly pay for SUD services;
- Being conducted by a state or local government unit receiving federal funds, if the federal funds may (but not necessarily are) be used for SUD services; or
- Being assisted by the Internal Revenue Service, such as granting tax exempt status or allowing tax deductions for contributions to the program.

Part 2 applies to any records held by a Part 2 program, "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), and including patient identifying information..." Patient identifying information includes "name, address, Social Security number, fingerprints, photograph, or

similar information by which the identity of a patient…can be determined with reasonable accuracy either directly or by reference to other information."[7]

The records of most health care providers are subject to HIPAA. Because Part 2 was specifically designed to provide additional privacy protections for people who have an SUD, Part 2 places greater restrictions on covered records than those provided by HIPAA. For example, HIPAA permits disclosures without consent for treatment, payment, and healthcare operations (often referred to as "TPO"). Part 2, on the other hand, requires consent for disclosures for TPO. Some providers are subject to both HIPAA and Part 2. To the extent that a provider is covered by both HIPAA and Part 2, the law that provides the greater privacy protection to the patient controls how the records can be used and disclosed, which will typically be Part 2. Furthermore, given that many providers are subject to both HIPAA and Part 2, a large part of the 2024 updates aim to create greater alignment to ease the compliance burden on regulated entities.

2024 Updates

Treatment, payment and healthcare operations (TPO) consent

As part of the 2024 updates to Part 2, patients now have an option to sign a single written consent that can authorize all future uses and disclosures of their Part 2 records for purposes of treatment, payment, and health care operations (TPO).[8] This means that with a TPO consent, a Part 2 program does not need to seek a new consent each time it seeks to disclose a patient's records for TPO.

The preamble and regulations provide additional clarification on what the content of this consent may look like. The TPO consent can list recipients broadly, such as "my treating providers, health plans, third-party payors, and people helping to operate this program" or a similar statement.[9] The purpose can simply be for "treatment, payment, or healthcare operations" and for the expiration date, the consent can list "end of treatment" or even "none".[10] In other words, it is permissible to have a TPO consent that does not have an expiration date.

The TPO consent has the potential to lessen barriers to care coordination for patients. It also, however, may reduce the protections on Part 2 records. Under the previous rule, if a patient signed a consent to share records, the Part 2 protections typically traveled with the records and limited how the recipient could use or disclose the records. Now however, once a recipient receives the Part 2 records in accordance with a TPO consent, if the recipient is a HIPAA covered entity or business associate, they may then redisclose the records in accordance with HIPAA, **except for** uses and disclosures for civil, criminal, administrative, and legislative proceedings ("legal proceedings") against the patient.[11] Any use in legal proceedings requires a Part 2 compliant court order or that the patient signs a separate Part 2 consent, which cannot be combined with a consent to use or disclose the records for any other purpose.[12]

This means that if the recipient of the records rediscloses the records in accordance with HIPAA, as permitted by the TPO consent, the records will lose their Part 2 protections as they are shared further downstream. The following example illustrates how this works in practice.

Bill receives treatment for an SUD at Star Treatment Center, a Part 2 provider. Bill signs a TPO consent authorizing his records to be shared with all his "treating providers, health plans, third-party payors, and people helping to operate the program." Bill is being treated concurrently for a heart condition at Community Hospital so pursuant to the TPO consent, Star Treatment shares his records with Community Hospital. Community Hospital is a HIPAA covered entity, so it can redisclose Bill's records in accordance with HIPAA, except for legal proceedings. Bill requires a surgery that Community Hospital cannot provide, so they refer Bill to a separate specialty cardiovascular surgical center. Community Hospital sends all of Bill's records, including those from Star Treatment Center, to the surgical center. Once those records are at the cardiovascular surgical center, there are no longer any Part 2 protections remaining on the records and they are only covered by HIPAA. If Bill was then involved in a legal proceeding and his records from the cardiovascular surgical center were subpoenaed, if the proper process under HIPAA was followed to obtain patient records for legal proceedings, the surgical center could disclose **all** of Bill's records, including the Part 2 records that had originated at Star Treatment.

This example illustrates how the TPO consent may both facilitate treatment and enhance care coordination, while also reducing the protections on Part 2 records as they are further disclosed. Patients do still have the option to sign a more limited Part 2 consent that will retain the Part 2 protections on the records.

Furthermore, when entities receive records based on a TPO consent, they are not required to segregate the records.[13] Because the disclosure permission on records received pursuant to a TPO consent are slightly different than typical HIPAA covered records (e.g. no use in legal proceedings) some method to demarcate or tag the records will likely still be necessary to determine which disclosures are permissible.

SUD Counseling Notes

The updates also established a new definition for SUD counseling notes, akin to the psychotherapy notes exception under HIPAA. These are "notes recorded (in any medium) by a part 2 program provider who is a SUD or mental health professional documenting or analyzing the contents of conversation during a private SUD counseling session or a group, joint, or family SUD counseling session and that are separated from the rest of the patient's SUD and medical record. SUD counseling notes excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date."[14] These are personal notes of the therapist; they are not part of the patients medical record or intended to be a separate repository for information that properly belongs in the medical record.

The exceptions for uses and disclosures on these notes without consent are more restrictive than the uses and disclosures on Part 2 records. The patient's written consent is required to disclose the notes except for certain limited exceptions including: (1) if the originator is using the notes for treatment, (2) internally for training purposes, and (3) for the Part 2 program to defend itself in a legal action brought by the patient.[15] Additional disclosures include those required by the Secretary of HHS to investigate Part 2 compliance, those permitted by court orders, pertaining to deceased patients such as vital statistics or cause of death, and limited oversight activities related to the originator of the notes.[16]

A written consent for SUD counseling notes may not be combined with any other consent except for another consent for SUD counseling notes, nor may a provider condition treatment or other services on signing a consent for SUD counseling notes.[17] For example, a provider could not combine a consent for SUD counseling notes with a consent to share Part 2 records for payment. A provider may, however, combine a consent to use SUD counseling notes for treatment and health care operations. Lastly, the clinician has discretion to share the notes with a patient and patients do not have a right to access SUD counseling notes.[18] This is in accordance with all of Part 2, which does not imbue patients with an inherent right of access to their records.[19]

The SAMSHA funded Center of Excellence for Protected Health Information (COE-PHI) has developed a resource with information on the new SUD counseling notes provision that may be helpful to consult for additional information on this new provision.

De-identification Standard and Disclosures to Public Health

Of particular interest to public health authorities is the provision that now expressly permits Part 2 programs to disclose de-identified data to public health authorities.[20] The de-identified patient information must meet the HIPAA standard for de-identification.[21] SAMHSA did not believe it had authority under the CARES act to extend this exception to identifiable data, even though HIPAA permits regulated entities to share identifiable information with public health authorities. As such, the rule is explicit that the permitted disclosures are limited to de-identified data.

Under HIPAA, there are two methods to render the information de-identifiable.[22] The first is the "safe harbor" method, where you can remove 18 enumerated identifiers that are listed in Part 2, and second is the "expert determination" method, where someone with appropriate statistical and scientific knowledge and experience of rendering information not individually identifiable applies those methods and determines there the risk of re-identification is very small. Under either method, there should be no reasonable basis to believe the information could be used to re-identify a patient. The U.S. Department of Health and Human Services (HHS) has provided extensive guidance on the HIPAA standard for de-identification.

In a separate but related provision on de-identification, the updates now require that Part 2 programs and lawful holders[23] of Part 2 records (with the exception of family, friends, and informal caregivers) must have policies and procedures in place to render patient identifying information de-identified in accordance with the HIPAA standard.[24]

Notice of Redisclosure and Scope of Consent

The 2024 updates now include a provision requiring certain information to accompany each disclosure made with a patient's written consent.[25] Specifically, each disclosure made with the patient's written consent must be accompanied by:

1. the statement "42 CFR part 2 prohibits unauthorized use or disclosure of these records"[26], and
2. a copy of the consent or clear explanation of the scope of the consent.[27]

Note that with respect to bullet (1), the regulations also include a second option for a written statement that describes the protections and redisclosure permission on the records in greater detail.[28] However, regulated

entities may prefer the brevity of the shorter statement. And while the requirement to have a notice accompanying disclosures is not new, the required language has changed, so Part 2 programs will need to review existing documents to ensure they comply with the new language.

Including a copy of the patient's consent or a clear explanation of the scope of the patient's consent provides the recipient of the records with the information the recipient needs to understand the redisclosure permissions that may be available. Previously, Part 2 protections typically traveled with the Part 2 records. With the new provision allowing patients to sign a one-time consent for all future disclosures for TPO, the Part 2 protections on some records are more limited. Clarifying the scope of the patient's consent is essential, so the entity receiving records can understand the protections and redisclosure permission on the patient's records. The following example illustrates this:

> Jack and Jill are each receiving treatment for SUD at Star Treatment Center. Jack signs a one-time consent to share information with Community Hospital for treatment, where he is receiving medical care. Jill signs a TPO consent for Star Treatment Center to share her records for all future uses and disclosures for TPO. Jill is also receiving medical care at Community Hospital and Star Treatment Center shares her records. For both Jack and Jill, Star Treatment Center forgets to include a copy of the consent or a description of the scope of consent. Community Hospital then receives requests for both Jack and Jill's records from a surgery center. Community Hospital does not know what kind of consent Jack and Jill each signed, and the hospital is unsure whether to disclose the records. If Community Hospital sends both Jack and Jill's records to the surgery center, that is permissible with Jill's TPO consent, but not with the one-time consent Jack signed. On the other hand, if Community Hospital refuses to share either Jack or Jill's records, that is the correct response for Jack's records due to the type of consent he signed, but not for Jill's records. In fact, Community Hospital could be engaging in information blocking if it does not share Jill's records.

This example underscores the importance of Part 2 programs having policies in place to notify recipients of Part 2 records that there are limitations on the uses and disclosures of Part 2 records, as well as provide recipients with a copy of the patient's consent or scope of consent. Furthermore, entities that receive Part 2 records will want to make sure they have policies in place to (1) confirm that the Part 2 program provided the scope of consent and (2) document it. This will ensure that the receiving entity only uses and discloses the records in line with the patient's consent.

The COE-PHI has developed a resource with more information on the notice to accompany disclosures that may be helpful to consult for additional information on this new provision.

Breach Notification Rule

The 2024 updates extended the HIPAA breach notification rule to Part 2 programs with respect to breaches of unsecured records.[29] The definition of "breach" is adopted by reference from the HIPAA regulations.[30] A breach under Part 2 includes a use or disclosure of Part 2 records that violates Part 2.[31]

Many Part 2 programs may also be covered by HIPAA, and thus familiar with the breach notification rule. Part 2 programs that are unfamiliar with the breach notification rule should consider consulting guidance from HHS

for additional clarification. For example, HHS provides an overview of the breach notification rule, including the requirement that affected individuals and the secretary of HHS be notified of breaches, as well as information on the process for notifying HHS if an entity discovers a breach of unsecured information.

The breach notification rule does not apply to Qualified Service Organizations (QSOs). QSOs are similar in concept to a HIPAA business associate and provide certain qualifying services to and have a written agreement in place with a Part 2 program. HIPAA business associates are directly liable for a breach of a patient's unsecured protected health information. SAMSHA stated in the updates, however, that it did not have statutory authority to make QSOs directly liable for breaches.[32]

SAMSHA did note that it expected Part 2 programs to address breach notification in its contractual provisions with QSOs. Even if the QSO is not directly liable for the breach, the Part 2 program must still notify a patient(s) of the breach. Specifically, SAMSHA stated that "[a] part 2 program would not be responsible for breaches by QSOs or business associates. However, the part 2 program is responsible under this rule for having in place contractual requirements to ensure that it is timely notified of a breach by such entities so that it can meet its obligations to notify affected individuals."[33] Lawful holders of Part 2 records are also not subject to breach notification requirements.[34]

Required Policies and Procedures and Complaint Process

Part 2 programs and lawful holders are required to have formal policies and procedures in place to protect both paper and electronic records.[35] Specifically, the regulations require policies to address the following:

(i) Paper records, including:

(A) Transferring and removing such records;

(B) Destroying such records, including sanitizing the hard copy media associated with the paper printouts, to render the patient identifying information non-retrievable;

(C) Maintaining such records in a secure room, locked file cabinet, safe, or other similar container, or storage facility when not in use;

(D) Using and accessing workstations, secure rooms, locked file cabinets, safes, or other similar containers, and storage facilities that use or store such information; and

E) Rendering patient identifying information de-identified in accordance with the requirements of 45 CFR 164.514(b) such that there is no reasonable basis to believe that the information can be used to identify a particular patient.

(ii) Electronic records, including:

(A) Creating, receiving, maintaining, and transmitting such records;

(B) Destroying such records, including sanitizing the electronic media on which such records are stored, to render the patient identifying information non-retrievable;

(C) Using and accessing electronic records or other electronic media containing patient identifying information; and

(D) Rendering the patient identifying information de-identified in accordance with the requirements of 45 CFR 164.514(b) such that there is no reasonable basis to believe that the information can be used to identify a patient.

There is an exception to these requirements for lawful holders of Part 2 records who are family, friends, and other informal caregivers.[36] Nevertheless, SAMHSA does state that it expects these caregivers to "recognize some responsibility to safeguard these sensitive records."[37]

Furthermore, SAMSHA extended the HIPAA Privacy rule's provisions on complaints to Part 2.[38] Patients will now have the right to file a complaint with a Part 2 program or directly with the Secretary of HHS.[39] A part 2 program or provider may not retaliate against a patient for filing a complaint. Part 2 programs that are also HIPAA covered entities will already have policies in place to address this provision. Part 2 programs that are not HIPAA covered, however, will need to develop new policies and procedures to establish a complaint process.

Conclusion

The 2024 updates made significant changes to the Part 2 rule. These changes, as well as others not directly addressed in this resources, will impact every Part 2 program and provider. Entities will need to be in full compliance by February 16, 2026. Because Part 2 programs can be liable for civil money penalties and enforcement authority has moved to the Office of Civil Rights (OCR), which has taken a very active role in enforcing HIPAA for decades, Part 2 programs should prioritize timely compliance with the updates. Part 2 programs and providers will need to review the changes, update their policies and procedures, and train their staff on the changes.

Additional resources on data and privacy can be found on the Network's website.

This document was developed by Meghan Mead, Deputy Director, Network for Public Health Law—Mid-States Region. The Network promotes public health and health equity through non-partisan educational resources and technical assistance. These materials provided are provided solely for educational purposes and do not constitute legal advice. The Network's provision of these materials does not create an attorney-client relationship with you or any other person and is subject to the Network's Disclaimer.

SUPPORTERS

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[1] Confidentiality of Substance Use Disorder (SUD Patient Records), 89 Fed. Reg. 12472 (February 16, 2024).

[2] 42 C.F.R § 2.2(b)(2).

[3] 42 C.F.R. § 2.11.

[4] *Id.*

[5] *Id.*

[6] 42 C.F.R. § 2.12(b).

[7] 42 C.F.R. § 2.11.

[8] 42 C.F.R. § 2.31.

[9] 42 C.F.R. § 2.31(a)(4)(i).

[10] 42 C.F.R. § 2.31(a)(5)(ii); § 2.31(a)(7).

[11] 42 C.F.R. § 2.33(b)(1).

[12] 42 C.F.R § 2.31(d); see also 42 C.F.R. § 2.64, 2.65.

[13] 42 C.F.R. § 2.12(d)(2)(i)(C).

[14] 42 C.F.R. § 2.11.

[15] 42 C.F.R. § 2.31(b).

[16] 42 C.F.R. § 2.31(b).

[17] 42 C.F.R. § 2.31(b)(2) and (3).

[18] Confidentiality of Substance Use Disorder (SUD) Patient Records, 89 Fed. Reg. 12506 (February 16, 2024).

[19] *Id.*

[20] 42 C.F.R. § 2.54.

[21] 42 C.F.R. § 2.54 (b).

[22] 45 C.F.R. **§ 164.514.**

[23] Lawful holder means a person who is bound by this part because they have received records as the result of one of the following: (1) Written consent in accordance with § 2.31 with an accompanying notice of disclosure or (2) One of the exceptions to the written consent requirements in 42 U.S.C. 290dd–2 or this part. 42 C.F.R. **§ 2.11.**

[24] 42 C.F.R. **§** 2.16(a)(1)(ii)(D).

[25] 42 C.F.R. **§ 2.32.**

[26] 42 C.F.R. **§ 2.32(a)(2). Note that the regulations also include a second option for a written statement that describes the protections and redisclosure permission on the records in greater detail.**

[27] 42 C.F.R. **§ 2.32 (b).**

[28] 42 C.F.R. **§ 2.32(a)(1).** ***"This record which has been disclosed to you is protected by Federal confidentiality rules (42 CFR part 2). These rules prohibit you from using or disclosing this record, or testimony that describes the information contained in this record, in any civil, criminal, administrative, or legislative proceedings by any Federal, State, or local authority, against the patient, unless authorized by the consent of the patient, except as provided at 42 CFR 2.12(c)(5) or as authorized by a court in accordance with 42 CFR 2.64 or 2.65. In addition, the Federal rules prohibit you from making any other use or disclosure of this record unless at least one of the following applies:***
(i) Further use or disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or as otherwise permitted by 42 CFR part 2.
(ii) You are a covered entity or business associate and have received the record for treatment, payment, or health care operations, or
(iii) You have received the record from a covered entity or business associate as permitted by 45 CFR part 164, subparts A and E.
A general authorization for the release of medical or other information is NOT sufficient to meet the required elements of written consent to further use or redisclose the record (see 42 CFR 2.31)."

[29] 42 C.F.R. **§ 2.16(b).**

[30] 42 C.F.R. **§ 2.11.**

[31] Confidentiality of Substance Use Disorder (SUD Patient Records), 89 Fed. Reg. 12496 (February 16, 2024).

[32] Confidentiality of Substance Use Disorder (SUD Patient Records), 89 Fed. Reg. 12504 (February 16, 2024).

[33] Confidentiality of Substance Use Disorder (SUD Patient Records), 89 Fed. Reg. 12520 (February 16, 2024).

[34] *Id.*

[35] 42 C.F.R. **§ 2.16.**

[36] 42 C.F.R. **§ 2.16(a)(2).**

[37] Confidentiality of Substance Use Disorder (SUD Patient Records), 89 Fed. Reg. 12520 (February 16, 2024).

[38] Confidentiality of Substance Use Disorder (SUD Patient Records), 89 Fed. Reg. 12495 (February 16, 2024).

[39] 42 C.F.R. **§ 2.4.**