THIRD HORIZON STRATEGIES

Demystifying 42 CFR Part 2 Confidentiality Regulations for Integrated Care Providers

1302 BHI Learning Collaboratives

Presented by: Mindy Klowden, MNM,
Managing Director for Behavioral Health

About Us

Third Horizon Strategies is a boutique advisory firm focused on shaping a future system that actualizes a sustainable culture of health nationwide. The firm offers a 360º view of complex challenges across three horizons – past, present, and future– to help industry leaders and policymakers interpret signals and trends; design integrated systems; and enact changes so that all communities, families, and individuals can thrive.

The THS behavioral health team helps stakeholders improve systems so that all individuals can access the care they need, when and where they need it. The firm provides facilitation services, research, policy analysis, strategy, alternative payment model design, and data analytics that promote behavioral health, increase quality, and improve outcomes.

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Learning Objectives

Participants will identify what 42 CFR Part 2 is, and why the regulation was created.

Participants will gain a better understanding of recent changes to federal regulations related to exchanging behavioral health information.

Participants will determine any changes needed in workflows, electronic health records management, or compliance practices.

Legal Disclaimer

The following presentation is provided for informational purposes only and is not meant to provide legal advice.

The information presented is current as of today, but additional federal guidance is expected.

42 CFR Part 2: The Basics

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What is it?

- Title 42 of the Code of Federal Regulations (CFR) Part 2: Confidentiality of Substance Use, A.K.A. 42 CFR Part 2, is a federal regulation that restricts the disclosure and use of patient records maintained in connection with the performance of any federally-assisted substance use disorder (SUD) treatment program.
- It was first promulgated in 1975 but has been modified multiple times.

What does it do?

- Protects the confidentiality of SUD patient records by restricting the circumstances under which Part 2 covered programs or other lawful holders can disclose such records.
- Requires written patient consent (may be paper or electronic).

Who does it apply to?

- Part 2 applies to SUD treatment records from certain federally assisted SUD treatment programs.

Why Was 42 CFR Part 2 Implemented?

Part 2 is intended to ensure that a patient receiving treatment for a Substance Use Disorder (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 applies to SUD treatment records from certain federally assisted SUD treatment programs, based on two requirements

"Federally assisted" (defined at § 2.12 (b))

- Authorized to conduct maintenance treatment or withdrawal management
- Registered to dispense buprenorphine or other controlled substances for SUD treatment
- Authorized as a provider in Medicare program
- Conducted by any federal department or agency (exception: military)
- Conducted by a state or local government that receives federal funds, like a block grant
- Recipient of federal financial assistance
- Granted tax-exempt status, or authorized by IRS to allow income tax deductions for contributions to the program

A "program" (defined at § 2.11)

- An individual, entity (other than a general medical facility), or an identified unit in a general medical facility that "holds itself out" as providing and does provide diagnosis, treatment, or referral for treatment for a SUD.
- When dealing with a general medical facility… It is the unit or medical personnel that is the "program" - NOT the whole general medical facility

If only one requirement is met, such as a substance use disorder treatment provider that is not federally assisted, it would not be considered a "Part 2 Program."

“Holds Itself Out”

SAMHSA has established the definition of “holds itself out” and is defined as any activity that would lead one to reasonably conclude that the individual or entity provides substance use disorder diagnosis, treatment, or referral for treatment, including but not limited to:

- Authorization by the state or federal government (e.g., licensed, certified, registered) to provide, and does provide, such services
- Advertisements, notices, or statements relative to such services or
- Consultation activities relative to such services.

Does 42 CFR Part 2 Apply to Medication-Assisted Treatment?

Physicians in general medical facilities who receive a DATA-2000 waiver to prescribe buprenorphine are considered federally assisted because of their waiver from the federal government.

- In December 2022, the DATA-2000 (or X-waiver) was repealed, and now a prescriber is authorized to offer buprenorphine for MAT with a general DEA-controlled substance registration. It is safe to assume that holding such a general registration would meet this first prong of analysis.

However, they will only be considered a "program" covered by Part 2 if:

- They work in the identified SUD unit of the general medical facility, which holds itself out as providing SUD services; or
- Their primary function is providing SUD diagnosis, treatment, or referral for treatment, and they are identified as such.

Remember, if only one requirement is met, such as a substance use disorder treatment provider that is not federally assisted, it would not be considered a "Part 2 Program."

Does 42 CFR Part 2 Apply to Medication-Assisted Treatment?

Example of a provider whose primary function is not SUD services

- Dr. Cohen is a provider at 123 Health. Occasionally, Dr. Pierce encounters patients with opioid use disorder and provides MAT with buprenorphine. However, he does this only for a handful of patients and it does not constitute his primary function at 123 Health.

Dr. Cohen is not covered by 42 CFR Part 2

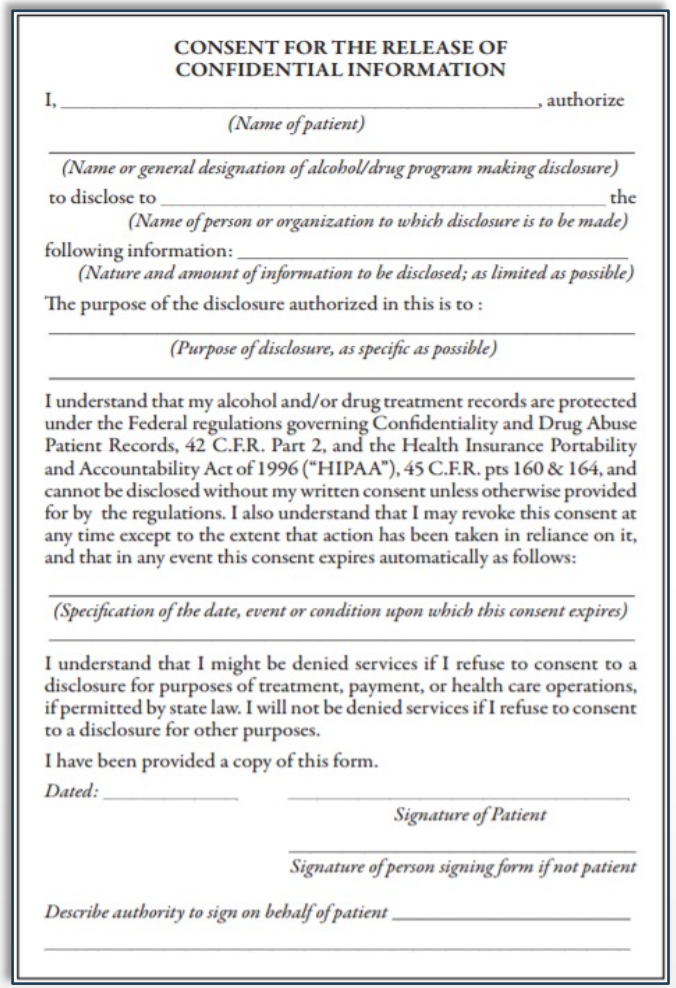
Example of provider whose primary function is SUD services

- Dr. Schuster, an addiction specialist at XYZ Health Center, only treats patients with SUDs. Typically, Dr. Schuster uses controlled substances for detoxification or maintenance treatment of a patient's SUD.

Dr. Schuster is covered by 42 CFR Part 2

Required Elements for Consent Form (Section 2.31)

- Name of the patient
- Name of the program making the disclosure
- Recipient of the information
  - To specify all future uses for TPO, the regulations suggest the following text for Recipient: “My treating providers, health plans, third party payers and people helping to operate this program”
- The specific purpose or need for the disclosure
  - To specify all future uses for TPO, the regulations suggest: “For Treatment, Payment and Health Care Operations”
- How much and type of information to be disclosed



CONSENT FOR THE RELEASE OF CONFIDENTIAL INFORMATION

I, _____, authorize
(Name of patient)

_____
(Name or general designation of alcohol/drug program making disclosure)

to disclose to _____ the
(Name of person or organization to which disclosure is to be made)

following information: _____
(Nature and amount of information to be disclosed; as limited as possible)

The purpose of the disclosure authorized in this is to :

_____
(Purpose of disclosure, as specific as possible)

_____

I understand that my alcohol and/or drug treatment records are protected under the Federal regulations governing Confidentiality and Drug Abuse Patient Records, 42 C.F.R. Part 2, and the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), 45 C.F.R. pts 160 & 164, and cannot be disclosed without my written consent unless otherwise provided for by the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that in any event this consent expires automatically as follows:

_____
(Specification of the date, event or condition upon which this consent expires)

_____

I understand that I might be denied services if I refuse to consent to a disclosure for purposes of treatment, payment, or health care operations, if permitted by state law. I will not be denied services if I refuse to consent to a disclosure for other purposes.

I have been provided a copy of this form.

Dated: _____ _____
Signature of Patient

_____
Signature of person signing form if not patient

Describe authority to sign on behalf of patient _____

_____

Required Elements for a Consent Form, continued

- The patient's right to revoke the consent in writing and exceptions to the right to revoke
  - To specify all future uses for TPO, the regulations suggest: "None" or "At the end of my treatment"
- The program's ability to condition treatment, payment, enrollment, or eligibility of benefits on the patient
- The date, event, or condition on which the consent expires
- The signature of the patient (and/or other authorized person)
- The date that the consent is signed
- Notice of redisclosure per HIPAA
  - To specify all future uses for TPO, the regulations say a notice of redisclosure needs to be on the consent form. They provide the following language: "Patient record may be re-disclosed in accordance with the permissions contained in the HIPAA regulations except for uses and disclosures for civil, criminal, administrative and legislative proceedings against the patient."

Medical Emergency Exception

- Part 2 permits disclosures to medical personnel without written consent to treat a medical emergency.
- Great deference has been given to medical personnel concerning their decisions about when a person in their care is in a medical emergency.
- The regulations do not explicitly define a medical emergency, but SAMHSA has indicated that a 'bona fide medical emergency' most often refers to a situation in which:
  - An individual requires urgent clinical care to treat an immediately life-threatening condition (e.g., heart attack, stroke, overdose).
  - It is infeasible to seek the individual's consent to release relevant, sensitive SUD records before administering potentially life-saving care.
  - Declared emergencies resulting from natural disasters (e.g., hurricanes) that disrupt treatment facilities and services are considered a medical emergency.

This year, the federal government made substantive changes

- 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, announced a final rule modifying the Confidentiality of Substance Use Disorder (SUD) Patient Records regulations at 42 CFR part 2 (“Part 2”).
- With this final rule, HHS is implementing the confidentiality provisions of section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which requires the Department to align certain aspects of Part 2 with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Rules and the Health Information Technology for Economic and Clinical Health Act (HITECH).
- The new rule goes into effect on April 16, 2024, and organizations have two years to comply.
- New SUD anti-discrimination requirements are enacted as part of the CARES Act, but these have yet to be promulgated in regulation.

How Does the Feb. 2024 Final Rule Align 42 CFR Part 2 with HIPAA?

Domain	Alignment
Patient Consent and Disclosure	• Allows single consent for all future uses and disclosures for treatment, payment, and operations (TPO) • Allows redisclosure for TPO purposes as permitted by the HIPAA regulations until the patient revokes the single consent in writing.
Counseling Notes	• SUD counseling notes are separated from the patient's record, like psychotherapy counseling notes under HIPAA
Notice of Privacy Practices (NPP)	• Modifies Part 2 to track the HIPAA NPP requirements, excluding those elements that do not apply.
De-identification and Data Breach	• Applies the HIPAA De-Identification Standard (45 C.F.R. §164.514(b)) • Clarifies that the HIPAA Breach Notification Rule will apply to breaches of unsecured substance use disorder records in the same manner as the rule applies to a HIPAA covered entity with unsecured protected health information.
Penalties	• Updates the penalties for wrongful use and disclosure of SUD records to align with the civil and criminal penalties under HIPAA.

How Does the Feb. 2024 Rule Change Impact Electronic Health Records?

- Section 2.12 states that data segmentation and record segregation is not required by Part 2 programs*, covered entities and business associates when they receive Part 2 records based on a single consent for all future TPO purposes.
  - The previous requirement to segment Part 2 data was one barrier that kept Part 2 programs from sharing their data with non-Part 2 programs - even when consent was in place.
- However, the information received is still considered a Part 2 record.
- Therefore, the EHR may still need to ”segregate” or “tag” the Part 2 data to comply with the requirement that when Part 2 data is re-disclosed, it be accompanied by a copy of the consent or a clear explanation of the scope of the consent provided.
  - EHRs that have received ONC Certification may have the ability to segment this information using Data Segmentation For Privacy (DS4P)
  - In cases where Part 2 and non-part 2 information are not being segregated (for example, lab results, medications, etc.), the EHR could be configured to include the required re-disclosure notification on all outbound documents. For example, as a footer on all outbound Continuity of Care (CCD) documents in case they contain Part 2 information.

* Segmentation of SUD Counseling Notes is still required in the updated regulations. However, it is assumed that these notes will not be widely shared by Part 2 programs just as psychotherapy notes are rarely shared among HIPAA covered entities.

How Does the Feb. 2024 Rule Change Impact Health Information Exchange?

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Former Part 2 Rule

- Under the former Part 2 rule, Health Information Exchanges (HIE) were considered Intermediaries and, as such, could receive data from Part 2 organizations without patient consent so long as they had a Qualified Service Organization Agreement (QSOA) with each Part 2 organization. However,
  - The HIE could not make that data available to their participants without first obtaining patient consent (which could be broadly stated such as “All my treating providers”) and
  - The provider receiving the Part 2 data was not able to redisclose that information for non-treatment purposes without obtaining additional consent and
  - The HIE, upon patient request, was required to provide an accounting of disclosures for all providers who had access to their Part 2 data over the course of 2 years.
- While this did enable some HIEs to begin to share Part 2 data more broadly, the overhead of managing consent and access was considerable.

New Part 2 Rule

- Under the new Part 2 rule, HIPAA covered entities, business associates and Part 2 Programs are no longer considered intermediaries. Therefore,
  - since HIEs are typically setup to be business associates of the HIPAA covered entities they serve and
  - if a single consent is obtained for all future TPO purposes
  - Then no further consent is required if the recipient of the Part 2 data is covered by HIPAA and the disclosure is permitted by HIPAA’s rules

Bottom Line: HIEs will be less burdened under the new regulation to share Part 2 information with their participants so long as the disclosure is for TPO, complies with HIPAA rules, and contains the required Part 2 re-disclosure notification.

What Restrictions/Patient Protections are Still in Place for 42 CFR Part 2 Covered Programs?

- Restricts the use of records and testimony in civil, criminal, administrative, and legislative proceedings against patients, absent patient consent or a court order.
- Patients' SUD treatment records cannot be used to investigate or prosecute the patient without written patient consent or a court order.
- Records obtained in an audit or evaluation of a Part 2 program cannot be used to investigate or prosecute patients, without written consent of the patients or a court order
- Prohibits combining patient consent for the use and disclosure of records for civil, criminal, administrative, or legislative proceedings with patient consent for any other use or disclosure.
- Requires a separate patient consent for using and disclosing SUD counseling notes, when they are segregated from the main record. Otherwise, the general consent authorizes their release.
- Requires that each disclosure made with patient consent include a copy of the consent or a clear explanation of the scope of the consent.
- Creates a new right for patients to opt out of receiving fundraising communications.

Sharing Information Within an Integrated Care Team

The restrictions on disclosure in the regulations 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.

Per 42 CFR 2.12(c), there is a qualified exception for communication within a part 2 program or between a part 2 program and an entity having direct administrative control over that part 2 program.

Steps to Prepare for Compliance with the Final Rule

- Review and update policies and procedures related to the use and disclosure of SUD records to comply with this final rule and merge or combine with overlapping HIPAA policies as applicable
- Review and update all notices of privacy practices, patient consent forms, and release of information forms to comply with this final rule and consolidate as appropriate
- Review and update (or implement if one does not yet exist) a data breach notification policy and procedure and/or incident response plan applicable to SUD records that complies with the HIPAA Breach Notification Rule
- Develop a plan to train staff and any training materials on the changes being implemented to comply with this final rule
- Audit compliance with the modified Part 2 regulations
- Assess if EHR updates are needed so that all outbound CCDs contain the notice that 42 CFR Part 2 data on a CCD can not be used to investigate or prosecute the patient

When in Doubt

Sources and Resources

- HHS Fact Sheet on Rule Changes
- HHS Fact Sheet on 42 CFR Part 2 and HIPAA
- Federal Register
- The Legal Action Center
- Code of Federal Regulations
- The Center of Excellence for Protected Health Information
- Kent Strategic Advisors (Note: this firm provided THS with a legal review of this presentation)

Thank you!

Mindy Klowden, MNM

Managing Director for Behavioral Health

Mindy@thirdhorizonstrategies.com

(303) 884-2670