

Coordinating Care for Patients with Substance Use Disorders in Virginia: Privacy Considerations

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- This presentation provides an overview of applicable laws and common scenarios; it is not intended to be legal advice
- Please note that this webinar is being recorded
- Time permitting, we will be holding a Q&A session at the conclusion of today's presentation.
 - You may ask a question at any time throughout the presentation, using the Q&A text box
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 - Simply type in your question and click send
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- **Background on 42 C.F.R. Part 2**
- **Background on Other Health Privacy Laws**
- **Use Cases**
- **Frequently Asked Questions**
- **Additional Q&A** (*time permitting*)

- **Provide an understanding of federal and state privacy rules that apply to care coordination for patients with a substance use disorder (SUD)**
- **Address questions and challenges care coordinators may face when exchanging information with healthcare providers**

The Need for SUD-Specific Privacy Regulations

- Individuals with SUD continue to face stigma and discrimination in areas such as employment, education, housing, child care, and in the health care system.
- The fear of discrimination and legal consequences related to being identified as having a SUD may deter people from seeking and engaging in treatment.
- Federal and state privacy requirements aim to protect patients from any intended or unintended bias associated with their SUD data.
 - Developing and following protocols to ensure patient SUD data privacy is important not only for compliance with federal and state laws, but also for building a trusting patient-provider relationship.
 - Providers may choose to implement protocols that go beyond what is legally required in efforts to assure patients that their SUD data will not get into the wrong hands.

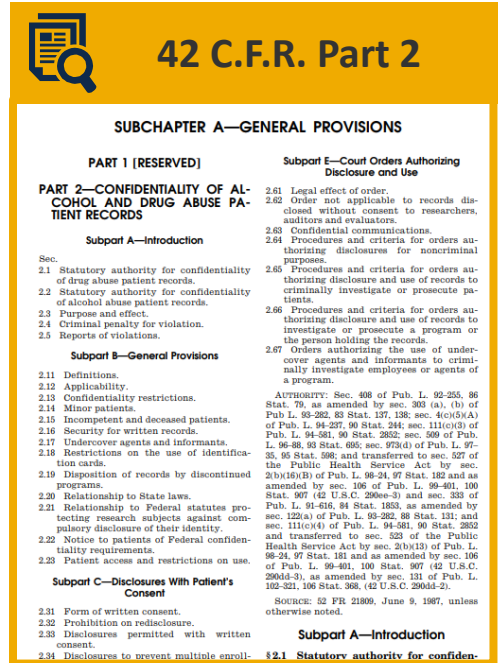
Today, we are focusing on the legal aspects of SUD data privacy, but providers should take a holistic view of privacy and develop protocols that reflect their patients' priorities and needs.

Background on 42 C.F.R. Part 2

What is 42 C.F.R. Part 2?

42 C.F.R. Part 2 refers to the federal SUD privacy regulations issued by the U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA). These regulations protect the confidentiality of SUD treatment records.

- Part 2 protects SUD patients from the potentially harmful consequences of having their SUD treatment records available to others (e.g., discrimination in areas such as employment and housing).
- Part 2 strictly prohibits sharing of SUD patient records except with the patient's specific written consent or under certain limited exceptions.
- SUD patient records and information may concurrently be subject to the Health Insurance Portability and Accountability Act (HIPAA), Part 2, and state laws.
- Although Part 2 has strict rules, it is generally not enforced by the federal government; instead, states play the lead enforcement role.



When Does 42 C.F.R. Apply?

Part 2 applies to (1) identifiable information (2) originating from a federally assisted program that (3) holds itself out as providing SUD diagnosis, treatment, or referral for treatment.

1

Identifiable Information. Information that identifies the patient as having (or having had) a SUD.

2

Federally assisted program. A provider organization that receives any assistance from a federal agency, including providers that participate in Medicare/Medicaid, has tax-exempt status, receives government grants, or is registered to dispense a controlled substance intended to treat a SUD. *The Department of Veterans Affairs and armed forces are typically excluded from Part 2.*

3

“Holds itself out” typically means that a provider organization advertises SUD services or has a specialty SUD license. If a provider organization offers both SUD and non-SUD care, then Part 2 applies to the unit that holds itself out as providing SUD care or staff identified as primarily providing SUD care.

Which Providers are Subject to Part 2?

Providers Subject to Part 2

- An opioid treatment program (OTP) participating in Medicaid/Medicare.
- A non-profit primary care practice that indicates on its website that it provides comprehensive SUD services.
- A psychiatric hospital participating in Medicaid/Medicare licensed to provide SUD treatment.



Providers That Are Not Subject to Part 2

- Emergency rooms that do not hold themselves out as SUD providers.
- Primary care/ mental health clinics that do not advertise their SUD services or have an SUD license.
- For-profit SUD providers that do not bill government payers (e.g., Medicare/Medicaid) and do not dispense controlled substances.
- Practitioners with Drug Addiction Treatment Act (DATA) of 2000 Waivers to provide medication-assisted treatment (MAT) with buprenorphine who do not hold themselves out as providing SUD care.



Providers should consult with their own legal counsel for questions about how 42 C.F.R. Part 2 applies to them

Part 2 information can be shared without written consent in the following scenarios:

1. Within a Part 2 program or to an entity with “direct administrative control” over the program, for SUD diagnosis, treatment or referral purposes (e.g., from a Part 2 provider to a hospital that oversees such providers)
2. To contractors known as “qualified service organization,” if needed to provide services to a Part 2 program (e.g., to the provider’s electronic health record vendor).
3. From a person who received the information under a valid authorization (i.e., “lawful holder”) to contractors, for purposes of payment or health care operations (e.g., from a health plan to a vendor that assists with claims processing)
4. For treatment during a medical emergency
5. For research
6. For audits and evaluation
7. When sharing information with the patient
8. Other narrow circumstances (e.g., to state or local authorities regarding suspected child abuse or neglect, in accordance with a court order after a hearing)



Part 2 Authorization Form Requirements

If none of the consent exceptions apply, and the provider feels that there is a need to share a patient's Part 2 information (e.g., for care coordination purposes), the provider must ask the patient to fill out an authorization form that includes the following components:



Source: 42 C.F.R. § 2.31

- **Name of patient**
- **Name or description of the source of information**
- **Description of the type of SUD information that may be disclosed**
- **Potential recipients**
 - Form generally must identify the recipient by name (name of legal entity is sufficient)
 - May use a description of the recipient, if the disclosure is made through and identifies an intermediary, such as a health information exchange, and recipient has a treating provider relationship with patient (e.g., the patient's primary care physician).
- **Purpose of disclosure** (e.g., information sharing)
- **Statement** that the authorization is subject to revocation at any time
- **Date, event or condition upon which consent will expire** (e.g., expiration at death is permitted)
- **Signature and date**

Section 3221 of the CARES Act made important changes to Part 2 regulations, including new flexibilities for sharing information. The federal government is supposed to issue implementing regulations effective March 27, 2021, but it has not yet done so.

- The Act states that if a patient signs a consent form, then the recipient of the information can redisclose Part 2 information for certain purposes without asking the patient to sign another form.
- Potential implications of the change
 - Increased enforcement of Part 2 since penalties that apply to HIPAA violations will now apply to Part 2 violations.
 - More flexibilities to Medicaid managed care organizations (MCOs)/ health plans and providers that receive Part 2 information. For example, MCOs could share information with another party (e.g., primary care provider) for care coordination purposes without having to get another consent.

Background on Other Health Privacy Laws

HIPAA is the primary healthcare privacy law and provides individuals with protections and rights related to their health information.

- HIPAA applies to the protected health information (PHI), which includes all individually identifiable health information, including
 - Demographic data
 - Medical histories
 - Test results
 - Insurance information
 - Other information used to identify a patient or provide healthcare services or healthcare coverage

What kind of organizations are subject to HIPAA?

HIPAA applies to PHI from:

- “Covered entities”, i.e., health plans, health care providers, and health care clearinghouses. Both Medicaid agencies and Medicaid MCOs are considered health plans
- “Business associates” (contractors) of covered entities



Can information be shared without patient consent?

HIPAA permits covered entities to share information without patient consent in the following instances:

- For its own treatment, payment, or health care operations
- When sharing information with a provider for treatment purposes
- To another covered entity for payment purposes
- To another covered entity for “health care operations” of the recipient, if both parties have a relationship with the patient and the disclosure relates to such relationship



Note: “Treatment” includes care coordination performed by a provider and “health care operations” includes care coordination by a health plan.

- Under Virginia law, minors can consent to the receipt of:
 - SUD and mental health services (parent must also sign for inpatient SUD treatment)
 - Services related to birth control, family planning, pregnancy, and sexually transmitted diseases.
- Who should sign the authorization form when consent for sharing of SUD data is required?
 - The minor should sign, if the SUD data relates to a “minor consent” service (as noted above)
 - Both the minor and the parent/guardian should sign if it is an inpatient SUD or inpatient psychiatric data
 - Otherwise, the parent/guardian should sign the authorization

Under state (but not federal law), parents have a right to their minor’s SUD data, unless treating professional determines that disclosure would be reasonably likely to cause substantial harm to the minor or another person.

Source: Virginia Code §§ 20-124.6, 32.1-127.1:03, 54.1-2969; 12 VAC 35-115-80.

Other Notable Privacy/Data Sharing Laws

| | Who does this apply to? | Implications for Care Coordinators or SUD Providers |
|---|---|---|
| VA Health Records Privacy Act <i>Code of Virginia § 32.1-127.1:03</i> | <ul style="list-style-type: none"> Hospitals and other provider types (e.g., licensed substance abuse treatment practitioners) | <ul style="list-style-type: none"> Generally consistent with HIPAA requirements for sharing information for the purposes of care coordination. Part 2 supersedes state law. <ul style="list-style-type: none"> While the state provides exceptions for when consent is needed, providers would need to comply with Part 2 if the relevant information is subject to Part 2. State requirements provide additional guidance on what consent forms for information sharing must include. |
| VA Mental Health Privacy Regulation <i>12 VAC 35-115-80</i> | <ul style="list-style-type: none"> Providers licensed, funded, or operated by the Department of Behavioral Health and Developmental Services (DBHDS) | |
| Federal Information Blocking Rule | <ul style="list-style-type: none"> All health care providers | <ul style="list-style-type: none"> Effective April 5, 2021, providers must disclose electronic health information (EHI) when requested, unless one of eight exceptions apply. Providers could be penalized for not sharing information they are legally required to share. |

NOTE: On March 2, 2021, Governor Northam signed the Virginia Consumer Data Protection Act (CDPA) into law, however, this does not apply to health plans, providers, or care coordinators.

See Appendix for additional information on all laws/regulations on this page

Who does Part 2 apply to?

- Federally assisted providers that hold themselves out as SUD treatment providers—generally meaning, they advertise SUD services or have a specialty SUD license

When is written consent required to share Part 2 information?

- Part 2 generally requires the patient's consent for disclosures for treatment/care coordination purposes. There are some instances where consent is not required (e.g., a medical emergency)

What about HIPAA and Virginia law?

- HIPAA and Virginia law generally allow disclosures of SUD data for treatment/care coordination purposes without consent
- But, Part 2 supersedes HIPAA and VA law when it applies

Use Cases

Scenario



- A minor with SUD receives MAT from a Part 2 provider.
- The minor's parent has concerns about MAT and asks the Part 2 provider to share information about the minor's treatment.

Analysis of Applicable Laws

- Virginia law generally gives parents the right to obtain information about their children's treatment.
- But Part 2 overrides state law and prohibits disclosure to the parent unless the minor "lacks the capacity" to make a rational choice.

Possible Options/Strategies

- Minor must consent to disclosure of Part 2 information to the parent, unless they "lack the capacity" to make a rational choice (may include the instance where a minor is in severe withdrawal).

Related Question: If Medicaid MCO has the minor's information and both the minor and parent are members, can the MCO disclose information to the parent?

- Unlikely under current law, even if minor consented to disclosure to the plan.

Scenario



- An adult patient of a Part 2 provider declines to sign a consent form that allows for disclosure of the patient's SUD to the patient's Medicaid MCO for purposes of care coordination.
- A care coordinator with the Medicaid MCO seeks information from the Part 2 provider, which declines to provide it.
- The patient did, however, sign a consent form to allow the Part 2 provider to bill the MCO for SUD treatment services.

Analysis of Applicable Laws

- Consent must be voluntary.
- Neither the Part 2 provider nor the MCO can require the patient to sign a consent form.
- Part 2 provider needs patient consent to bill the MCO for services.

Options/Strategies

- Limit the number of consents a Part 2 provider asks the patient to sign.
 - MCO could contractually require the Part 2 provider to present a single consent form that allows disclosure for both payment and care coordination purposes.
 - If the patient refuses to sign the combined form, the provider could explain that the services would then need to be paid out-of-pocket.

If the provider does not hold itself out as a Part 2 provider, then they can share SUD data with the MCO about the member's use of SUD services without consent.

Scenario



- Mental health practitioner treats a Medicaid MCO member with schizophrenia.
- Based on evidence that the member’s medications are not being managed properly, a care coordinator with the MCO seeks information from the practitioner, but the practitioner refuses to correspond.

Analysis of Applicable Laws

- Practitioner is not subject to Part 2 if does not advertise or otherwise “hold out” as a provider of SUD treatment.

Other Considerations

- If mental health practitioner is not subject to Part 2, disclosure could be made in compliance with HIPAA and Virginia privacy laws.
- If practitioner maintains electronic records, the practitioner may have a potential obligation to disclose under the information blocking rule.

If the mental health practitioner offers some SUD treatment as part of a comprehensive care plan for the member, but does not hold itself out a Part 2 provider, it can share information on these SUD services.

Scenario



- Member of Medicaid MCO needs ongoing care from a Part 2 provider, and seeks transportation to that program.
- Part 2 provider that will treat the member will not coordinate with the MCO to arrange for such transportation.

Analysis of Applicable Laws

- Part 2 program cannot coordinate with the MCO for transportation without consent. Even though SUD treatment information is not being provided, the individual's status as a patient at a Part 2 program would be revealed.

Options/Strategies

- Primary care provider (PCP) or another organization not subject to Part 2 could arrange for the transportation.
 - If the PCP made the referral to the Part 2 provider or otherwise knows the patient will be receiving ongoing treatment, they could offer to arrange transportation.
 - Patient could convey necessary information to PCP/other organization and ask them to arrange transportation.
- Patient may give consent to have information shared only for purposes of providing transportation.
- If the transportation program operates as a subcontractor to the Part 2 provider, the provider could disclose to the program as a “qualified service organization.”

Q&A

Frequently Asked Questions

| | HIPAA | Part 2 |
|---|---|--|
| What type of information and entities are subject to the law? | <ul style="list-style-type: none"> Individually identifiable health information created or received by a covered entity (providers and health plans) or their business associates. | <ul style="list-style-type: none"> SUD information originating from a federally assisted program that holds itself out as a provider of SUD services. |
| When can information be shared without written consent? | <ul style="list-style-type: none"> For treatment, payment or health care operations (including care coordination, quality improvement), except for psychotherapy notes. Other permitted circumstances include research and public health. | <ul style="list-style-type: none"> In limited circumstances, including medical emergencies, research, audit, and evaluations. |
| Can a minor’s information be shared with third parties without their written consent? | <ul style="list-style-type: none"> Possibly <ul style="list-style-type: none"> A parent/guardian can consent on behalf of an unemancipated minor, unless the minor provided consent for the service. | <ul style="list-style-type: none"> No <ul style="list-style-type: none"> Disclosure may only occur with the minor’s consent; if the parent/guardian consented to the service itself then the consent of both the parent/guardian and minor is required. |
| Can a minor’s information be shared with a parent/ guardian without written consent? | <ul style="list-style-type: none"> Defers to state law. | <ul style="list-style-type: none"> No Disclosure permitted only if the minor consents to such disclosure or the minor lacks capacity to make a rational choice. |

The following VA-specific requirements are generally consistent with HIPAA requirements for sharing information for the purposes of care coordination. However, if Part 2 prevents disclosure, a provider may not share information, even if Virginia law and HIPAA would allow it.

| | VA Health Records Privacy Act <i>Code of Virginia § 32.1-127.1:03</i> | Mental Health Privacy Regulation <i>12 VAC 35-115-80</i> |
|--|---|---|
| Who does this apply to? | <ul style="list-style-type: none"> Hospitals and other provider types (e.g., licensed substance abuse treatment practitioners). | <ul style="list-style-type: none"> Providers licensed, funded, or operated by the Department of Behavioral Health and Developmental Services (DBHDS). |
| Are there exceptions for requiring consent? | <ul style="list-style-type: none"> Yes, <ul style="list-style-type: none"> When necessary for patient care To payers for reimbursement For health care operations purposes | <ul style="list-style-type: none"> Disclosures to <ul style="list-style-type: none"> Providers, health plans, DBHDS, and community services boards to give services to the patient or to obtain payment for a service DBHDS, community services boards, or other providers for preadmission screening or discharge planning |
| What must consent forms include? | <ul style="list-style-type: none"> In cases where patient authorization is required, the form must include certain elements, including the source and recipient of the information, an expiration date, and the purpose of disclosure. | <ul style="list-style-type: none"> Generally consistent with the Virginia Health Records Privacy Act, but also requires an indication whether the authorization applies to information created after execution. |

Virginia Consumer Data Protection Act (CDPA).

- Signed into law by Governor Northam on March 2, 2021.
- **Not relevant** to health plans and providers because does not apply to HIPAA covered entities/business associates, nonprofits, or state/local agencies.
- Does not apply to PHI or “health records” under Virginia law.

Federal Information Blocking Rule.

- Scheduled to go into effect on April 5, 2021.
- **Requires health care providers to disclose electronic health information (EHI) when requested**, unless one of eight exceptions apply.
- Potentially can require a provider to disclose EHI if applicable privacy law permits disclosure.
- Providers could be penalized for not sharing information they are legally required to share.

Q. Is an SUD diagnosis always subject to Part 2?

A. No. A SUD diagnosis is only subject to Part 2 if the diagnosis comes from a Part 2 program.

Q. Does 42 C.F.R. Part 2 protect information about former patients of a Part 2 program, even if those patients no longer receive SUD services?

A. Yes. Part 2 does apply to records that identify a patient as having had an SUD in the past if the record originates from a Part 2 program.

Q. Given the need to engage in telehealth during the pandemic, can a patient verbally consent to the disclosure of Part 2 records?

A. No. Part 2 requires written consent. Electronic signatures are allowed, but obtaining an electronic signature may require technical capabilities that are beyond the reach of many providers or patients.

- ◆ If a patient has a smart phone or access to a computer, the provider could send a consent form electronically. (Various free apps are available to “e-sign” documents)
- ◆ Provider could review the list of “permissible disclosures” under Part 2 to see if they can disclose records without consent (e.g., medical emergency)



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About

Jocelyn Guyer provides policy expertise, strategic advice and technical support to states, foundations and a range of clients on the successful implementation of the Affordable Care Act (ACA), delivery system reform, Medicaid and the Children's Health Insurance Program (CHIP).

With decades of health policy work, Jocelyn possesses a nuanced perspective on delivery system reform, coverage and eligibility issues, and IT systems. She has served as an advisor to the National Academy for State Health Policy and the American Academy of Pediatrics, among others.

Prior to joining Manatt, Jocelyn was a founding member and coexecutive director of the Center for Children and Families, a health policy center at Georgetown University. She provided advice and expertise to national policymakers and advocates on health policy and safety net programs.

Jocelyn managed CCF's review of federal health reform regulations and its annual 50-state survey on Medicaid and CHIP eligibility rules. During her tenure as a senior researcher at Georgetown University, Jocelyn helped Maryland implement the ACA and establish its marketplace.

As an associate director with the Kaiser Commission on Medicaid and the Uninsured, Jocelyn analyzed issues in healthcare for vulnerable Americans, including Medicaid waivers, the implications of the Medicare Part D drug benefit for impoverished seniors and people with disabilities, and the expected impact of transforming the financing of Medicaid.

At the Center on Budget and Policy Priorities, Jocelyn assisted states and advocates with implementing family-based coverage expansions, advised congressional offices on creation of CHIP initiatives, and designed policy initiatives to link Medicaid and other social supports. She also served as a legislative research assistant to the late Sen. Daniel Patrick Moynihan (D-NY).

Throughout her career Jocelyn has been a speaker at national gatherings of state officials, provider organizations, advocacy groups and foundations. She has presented to members of Congress, as well as state and local officials, on the future of children's coverage, transforming Medicaid and implementing federal health reform.



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About

Alexander Dworkowitz is a Manatt Health partner. He advises health care providers, managed care organizations, trade associations and pharmaceutical manufacturers on a wide variety of federal and state regulatory issues and transactional matters.

Prior to joining Manatt, Alexander served as a law clerk for the Honorable Alvin Hellerstein, U.S. District Court for the Southern District of New York. He was previously an associate in the litigation practice of an international law firm.

Before entering the practice of law, Alexander was a senior analyst with the health care team of the U.S. Government Accountability Office (GAO). He also worked as a staff writer for Hartford and New York City-based newspapers.