Substance Use Disorder Confidentiality and Updates to 42 CFR Part 2: A Two-Part Series
SUD Confidentiality: Overview and Update for SOR and SUD Providers, Part 1
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Acknowledgment

This webinar was created by the Health Law and Policy section of the UNH Institute for Health Policy and Practice, in our capacity as providers of technical assistance to the State Opioid Response (SOR) team at the NH Department of Health and Human Services in support of SOR vendors and the NH Doorways.
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She has practiced law for over 30 years, most recently serving as Legal Counsel to New Hampshire Governor Maggie Hassan and her senior health care policy advisor, working with the Governor on initiatives to expand access to health, mental health and substance use disorder services for New Hampshire citizens. Lucy is an experienced New Hampshire health care and regulatory attorney. Previously a shareholder in the firm of Rath, Young and Pignatelli, P.C., and Chair of the firm’s Healthcare Practice Group, Lucy assisted providers and businesses navigate the changing health care environment. Prior to private practice, Lucy served as an Assistant Attorney General in the New Hampshire Department of Justice and began her practice in the San Francisco offices of Brobeck, Phleger and Harrison.
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Agenda: Substance Use Disorder (SUD) Confidentiality Primer

42 CFR Part 2 Basics and Updates

What you need to know
Goals for Today

1. Reminder about basics of 42 CFR Part 2

2. Update on important changes in final 42 CFR Part 2 regulation
   • SAMHSA released a final rule on July 13, effective August 14, 2020.

3. Highlight future changes to 42 CFR Part 2 from CARES Act 2020
   • CARES Act amendments require implementing regulations that will not be published prior to March 27, 2021.

4. Tips
42 CFR Part 2
General Rule

- 42 CFR Part 2 regulations (Part 2) serve to protect patient records created by federally assisted programs for the treatment of substance use disorders (SUD).
- The information protected by 42 CFR Part 2 is any information disclosed by a covered program that identifies an individual directly or indirectly as having a current or past drug or alcohol problem, or as a participant in a covered program.
- With limited exceptions, 42 CFR Part 2 requires patient consent for disclosures of protected health information even for the purposes of treatment, payment, or health care operations.
42 CFR Part 2 Timeline

December 2018 - 1st presentation to Doorways on 42 CFR Part 2

July 2019 - 2nd presentation to Doorways on 42 CFR Part 2

August 2020 - Interim 42 CFR Part 2 rules published

Before March 27, 2021 – Additional 42 CFR Part 2 rules proposed (CARES Act)

December 2018 – July 2019
Doorways drafted consent forms and entered QSOA agreements

July 2020 – Interim 42 CFR Part 2 rules published

January 2021 – 3rd presentation to Doorways on 42 CFR Part 2

After March 27, 2021 – Additional 42 CFR Part 2 rules effective
Access and Transparency Developments

**Patient Access to Records:** “Right of Access” initiative continues

**HIPAA Privacy Proposed Rule:** December 10, 2020 new proposed rules enhancing ability to share protected health information for care coordination and care management

**Interoperability and Information Blocking Rule** (eff. April 5, 2021): requires health care providers to give patients access to their ePHI.

**Price Transparency** (effective 1/1/21 for hospitals; 1/1/23 for health plans): rule to help patients know how much their healthcare will cost in advance
COVID 19

- Federal and state orders during emergency relieved privacy restrictions to allow for new care pathways during COVID.
- Federal guidance from HHS waives certain HIPAA restrictions to allow for telehealth
- Federal guidance from SAMHSA clarifies emergency exception during COVID under 42 CFR Part 2
Privacy Restrictions
Potential Sources of Confidentiality/Privacy Restrictions

- Grants/Contracts
- Professional Responsibilities / Codes of Ethics
- Employer Policies
- Statutes and Regulations
- Client Requests
### Part 2 is Just Part of the Many Privacy and Confidentiality Laws

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Statute or Regulation</th>
<th>Scope</th>
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<tbody>
<tr>
<td>Federal</td>
<td>HIPAA Privacy Rules</td>
<td>Protects individually identifiable health information maintained by providers, payers and their contractors from disclosure. Heightened protections for psychotherapy notes.</td>
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<tr>
<td></td>
<td>42 CFR Part 2</td>
<td>Protects the confidentiality of substance abuse patient records from disclosure without express patient consent.</td>
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<td></td>
<td>FERPA</td>
<td>Protects education records</td>
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<tr>
<td>New Hampshire</td>
<td>RSA 332-1:1</td>
<td>Medical information in the medical records in the possession of any health care provider shall be deemed to be the property of the patient</td>
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<td>RSA 318-B:12-a</td>
<td>Protects reports and records of treatment of minors for drug dependency as confidential</td>
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<tr>
<td></td>
<td>RSA 330-A:32</td>
<td>Protects communications between mental health practitioners and patients as privileged</td>
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<td>RSA 330-C:26</td>
<td>Protects information held by a licensed alcohol or other drug use professional performing substance use counseling services unless permitted by 42 CFR Part 2</td>
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<td></td>
<td>RSA 135-C:19-a</td>
<td>Requires and/or permits disclosure of certain information by treating providers and community mental health centers to designated receiving facilities (DRFs) re: patients with SMI</td>
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Remind Me – Is there a difference between HIPAA and Part 2?

<table>
<thead>
<tr>
<th>HIPAA</th>
<th>42 CFR Part 2</th>
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<tbody>
<tr>
<td><strong>Applies to</strong></td>
<td>SUD patient records from federally-assisted “Part 2 programs”</td>
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<tr>
<td><strong>HHS</strong></td>
<td><strong>SAMHSA</strong></td>
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<tr>
<td><strong>Protects:</strong> privacy and security of general health information</td>
<td><strong>Protects:</strong> privacy and security of records identifying individual as seeking/receiving Substance Use Disorder (SUD) treatment</td>
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<tr>
<td><strong>Purpose:</strong> to protect health data integrity, confidentiality, and accessibility</td>
<td><strong>Purpose:</strong> to encourage people to seek Substance Use Disorder (SUD) treatment and reduce stigma through enhanced confidentiality</td>
</tr>
<tr>
<td><strong>Permits</strong> disclosures <em>without</em> patient consent for treatment, payment and healthcare operations and for public health purposes.</td>
<td><strong>Prohibits disclosures except with</strong> a patient consent for treatment, payment, and healthcare operations, with limited exceptions</td>
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Confidentiality Provisions in the Doorway Contracts

3.1.10.1 Develop and implement adequate consent policies/procedures for client-level data sharing and care planning with external providers

3.2 Obtain Consent forms from all clients served, either in-person, telehealth, or other electronic means, to ensure compliance with state and federal confidentiality laws

3.6.1 Create privacy notices and consent forms and submit them to the Department for review and approval

5.8 Meet Training Requirements for Staff/Subcontractors, including periodic trainings in practices and procedures to ensure compliance with information security, privacy or confidentiality in accordance with state and federal laws and rules

....and many more!
Doorways are Part 2 Programs

A Part 2 program is:
• An individual or entity (or a unit in a general medical care facility) that holds itself out as providing and does provide SUD treatment, diagnosis or referral for treatment; or
• Medical personnel or staff in a general medical facility whose primary function is the provision of SUD services and who are identified as SUD providers; and
• Is federally “assisted” (with the exception of some Veterans’ Administration services).
## The “Who” and “What”

<table>
<thead>
<tr>
<th><strong>Who is a Part 2 Patient?</strong></th>
<th>A <strong>Part 2 patient</strong> is any individual who has applied for or been given a diagnosis, treatment, or referral for treatment for a SUD at a Part 2 program.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What is Treatment?</strong></td>
<td>“<strong>Treatment</strong>” means the care of a patient suffering from a SUD, a condition which is identified as having been caused by the SUD, or both, in order to reduce or eliminate the adverse effects on the patient.</td>
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</tbody>
</table>
| **What Does Part 2 Protect?** | **Part 2 Protected Records** include:  
1) Any information that would identify a patient as a SUD patient either directly or by verification;  
2) Any information about a patient created, received or acquired by a Part 2 program for the purpose of treating alcohol or drug abuse, making a diagnosis for treatment, or making a referral for that treatment;  

*Unless* that person provides a written consent, or the disclosure meets another exception. |
42 CFR Part 2
Overview
Part 2 Requirements – Check List

I. Patient Records Security policies that meet the new Part 2 standards
II. Notice of privacy rights that meet Part 2 requirements
III. Non re-disclosure notices when Part 2 information disclosed with consent
IV. Qualified Service Organization Agreements when necessary
V. Compliant consent forms and disclosures pursuant to a valid exception
Part 2 Requirements – Details

I. Patient Records Security policies that meet the new Part 2 standards

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V. Compliant consent forms and disclosures pursuant to a valid exception
Security Polices (2.16)

- Part 2 program or lawful holder of Part 2 information must have formal policies and procedures to reasonably protect against unauthorized uses and disclosures of patient identifying information.

- Policies must ensure protection of paper and electronic records.

- Topics of policies should include transferring records, storing records, de-identification, etc.

- Should be included in health center’s general privacy policies and procedures.
Part 2 Requirements – Details

I. Patient Records Security policies that meet the new Part 2 standards

II. **Notice of privacy rights that meet Part 2 requirements**

III. Non re-disclosure notices when Part 2 information disclosed with consent

IV. Qualified Service Organization Agreements when necessary

V. Compliant consent forms and disclosures pursuant to a valid exception
Notice to Patients at time of admission to the Part 2 Program (2.22)

*Federal law protects the confidentiality of SUD patient records!*

A general description of the limited circumstances under which a Part 2 program may acknowledge an individual is present or disclose outside the program information identifying a patient as having or having had a SUD.

Violation of Part 2 is a crime and suspected violations may be reported.

Information related to patient’s commission of a crime on the premises or against personnel is not protected.

Reports of suspected child abuse and neglect are not protected.

A citation to the federal law and regulations and where a complaint can be made.

*May include summary of state law and additional consistent policies.*
Part 2 Requirements – Details

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Non-Redisclosure Warning: When are disclosures made?

Doorway Employees and Contracted Staff

- Unite Us
- MAT Provider
- Shelter
- Family
- Hospital ER
Non-Disclosure Notice – NEW

Each disclosure with consent must be accompanied by a non-disclosure notice

Is there a disclosure of part 2 information with a consent? If YES -

“This record which has been disclosed to you is protected by federal confidentiality rules (42 CFR Part 2). The federal rules prohibit you from making any further disclosures of this record unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or, is otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with substance use disorder, except as provided at 2.12(c)(5) and 2.65.”

“42 CFR part 2 prohibits unauthorized disclosure of these records”
## Part 2 Requirements – Details

<table>
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<td>V.</td>
<td><strong>Compliant consent forms and disclosures pursuant to a valid exception</strong></td>
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Patient Consent: Elements (2.31)

1) Name of the Patient
2) Names of Part 2 entities or providers making the disclosure
3) How much and what kind of information is to be disclosed including specific reference to SUD
4) “To Whom” is the disclosure being made?
5) The purpose of the disclosure
6) Right to revocation at any time going forward
7) The date, event or condition upon which the consent will expire.
Part 2 Consent - the details matter...

- The name of the individual(s) or
- The name of the entity(ies)

...to whom disclosure will be made.

To Whom

2021
Exceptions to 42 CFR Part 2’s Prohibition on Disclosure of SUD Information
When Can Part 2 Records be Shared?

- Internal Communications
  - Audit/Evaluation
  - Medical Emergency
    - Reporting suspected child abuse and neglect
- Court Order
  - Qualified Service Organization Agreement
  - No patient identifying information
- Crime on program premises or against program personnel
- Research
  - Written Consent
Part 2
Exception

Qualified Service Organization Agreement
A QSO is like a business associate – but a QSO can only disclose Part 2 information to agents or back to the Part 2 contracting provider. A QSO provides services to a Part 2 program, such as data processing, legal, accounting, “medical staffing or other professional services”, or population health management. Part 2 program can only share what’s necessary for QSO to perform services for the program.
QSOA Disclosure Flow

Part 2 Provider → QSO → Agent → Part 2 Provider
Part 2
Exception

Audit/Evaluation
Audit and Evaluation Exception

Audits when for compliance with rules, laws, polices and waivers
- Payer audit
- Audit by federal, state, local government
- Government by Medicare/Medicaid
- Audit by ACO or CMS-Regulated Entity

WITS
- NH DHHS requires a consent to enter GPRA information with identifiers in the WITS system.
- Consent is in a pdf that can be printed and included with privacy materials.
42 CFR Part 2
Changes
Key updates for the current moment!

- Relaxed “to whom” requirements
- Clarification on communications with non-Part 2 providers
- Shortened non redisclosure language
- Consent for ‘Payment and Healthcare Operations’
- Exceptions during COVID
<table>
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<tr>
<th>Record 2.11</th>
<th>Applicability 2.12(d)(2)(ii)</th>
<th>Consents (2.31)</th>
<th>PDMP</th>
</tr>
</thead>
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<td><strong>Excludes information conveyed orally to a non-Part 2 provider for treatment purposes with a patient consent even if written down.</strong></td>
<td><strong>A non-part 2 treating provider may “record information about a SUD and its treatment that identifies a patient.” This is not a Part 2 record.</strong></td>
<td><strong>General requirement for designating recipients:</strong> Allows patients to name a <strong>person or entity</strong> to which a disclosure can be made</td>
<td><strong>Part 2 Programs are permitted to enroll in a state prescription drug monitoring program (PDMP) and report SUD medication prescribed or dispensed consistent with state law.</strong></td>
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<td><strong>Means resulting medical record is not covered by Part 2</strong></td>
<td><strong>Part 2 records received by the non-Part 2 treating provider should be segmented, however.</strong></td>
<td><strong>Consent form no longer has to name a specific person at a non-treating entity.</strong></td>
<td><strong>Allows a treating provider to check a central registry to confirm the appropriateness of prescribed therapy.</strong></td>
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<tr>
<td><strong>Definition Change to Facilitate Care Coordination</strong></td>
<td><strong>Change to Facilitate Care Coordination</strong></td>
<td><strong>“To Whom” Simplified</strong></td>
<td><strong>Outpatient Treatment Providers</strong></td>
</tr>
<tr>
<td><strong>Consents for payment and health care operations</strong></td>
<td><strong>Agents and administration made easier</strong></td>
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**Activities include “care coordination and/or case management services in support of payment or health care operations.”**

**“to Housing Finance Authority”**
Payment and Health Care Operations by Consent

Patients can now consent to sharing Part 2 information for purposes of “payment and health care operations” with consent, lawful holders can disclose necessary information with their agents for such purposes.
Summary of Payment and Health Care Operations

Examples of permissible payment or health care operations activities under this section include:

- Billing, claims management, collections activities, ...related health care data processing;
- Clinical professional support services;
- Patient safety activities;
- Activities pertaining to: (i) The training of student trainees and health care professionals; (ii) The assessment of practitioner competencies; (iii) The assessment of provider or health plan performance; and/or (iv) Training of non-health care professionals;
- Accreditation, certification, licensing, or credentialing activities;
- Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits...;
- Third-party liability coverage;
- Activities related to addressing fraud, waste and/or abuse;
- Conducting or arranging for medical review, legal services, and/or auditing functions;
- Business planning and development;
- Business management and general administrative activities;
- Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;
- Resolution of internal grievances;
- The sale, transfer, merger, consolidation, or dissolution of an organization;
- Determinations of eligibility or coverage and adjudication or subrogation of health benefit claims;
- Risk adjusting amounts due based on enrollee health status and demographic characteristics;
- Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;
- Care coordination and/or case management services in support of payment or health care operations; and/or
- Other payment/health care operations activities not expressly prohibited in this provision.
Doorway Practice Tip

- Simplify consent forms - only require **entity** names in “to whom” section.
- No distinction between **treating** and **non-treating** providers – entity name is sufficient
- Include space to allow for consent to disclose to entity(s) for “payment and/or health care operations”. Can include health insurance and/or case management organizations

- Train staff
Future CARES Act Changes
CARES Act and Part 2


The Final Part 2 rules were intended to facilitate well-coordinated care for patients with SUD.
CARES Act Changes – 42 USC 290dd-2

- Consent still required for disclosure of SUD treatment records by a Part 2 Program.
- With a general consent, disclosures and redisclosures may be made consistent with HIPAA for treatment, payment and health care operations.
- Adopts HIPAA fines and penalties in the place of Part 2 enforcement mechanism.
- Prohibits use of SUD records in civil, criminal, legislative or administrative proceedings without a court order.
- Applies breach notification rules.
- Changes enforcement authority.
Practice Tip- CARES Act

WAIT FOR PROPOSED RULES

COMMENT ON PROPOSED RULES
Next Up – Session 2

Consents, telehealth, emergencies
Answer questions and hypos
Apply standards
Resources

Notice Prohibiting Redisclosure
Questions?
Appendix

Summary of 42 CFR Part 2 Rule Changes Effective
August 2020
Summary of Final Rule Changes

**Definitions** - Excludes certain oral communications and non-part 2 treatment records from the definition of “records.” To facilitate coordination of care activities between Part 2 programs and non-Part 2 providers.

**Applicability** - Information about an SUD recorded by a non-part 2 is not automatically rendered a medical record subject to Part 2.

**Segregated or Segmented records** - Non-Part 2 providers may record and segment or segregate information from paper or electronic Part 2 records received from Part 2 providers without its record becoming subject to Part 2. The segregated or segmented records remain subject to Part 2.

**Prohibition on redisclosure** - Non-Part 2 providers do not need to redact information in non-Part 2 records and may redisclose with express consent.

**Disclosures Permitted with Written Consent** - Disclosures for “payment and health care operations” are permitted with written consent; lists 18 qualifying activities, including care coordination and case management.

**Consent Requirements** - A patient may consent to the disclosure of their information for operations purposes to certain entities without naming a specific individual.
Summary of Final Rule Changes, cont.

Disclosures to Prevent Multiple Enrollments - Revises disclosure requirements to allow non-opioid treatment providers with a treating provider relationship to access central registries

Disclosures to Central Registries and PDMPs - Opioid treatment programs may disclose dispensing and prescribing data to prescription drug monitoring programs (PDMPs), subject to patient consent and State law.

Medical Emergencies - Authorizes disclosure of information to another Part 2 program or SUD treatment provider during State or Federally-declared natural and major disasters

Research - Disclosures for research under Part-2 are permitted by a HIPAA-covered entity of business associated to those who are neither HIPAA covered entities, nor subject to the Common Rule

Audit and Evaluation - Clarifies what activities are covered by the broad audit and evaluation exceptions

Undercover Agents and Informants - Extends court-ordered placement of undercover agents to 12-months

Disposition of Records - When an SUD patient sends an incidental message to the personal device of an employee of a Part 2 program, the employee may “sanitize” the device by deleting the message