

# **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**

February 2021 Recording

By:

Lucy C. Hodder, JD

[Lucy.Hodder@unh.edu](mailto:Lucy.Hodder@unh.edu)

Professor of Law, UNH School of Law  
Institute for Health Policy and Practice

Lauren LaRochelle, JD

[lauren.larochelle@unh.edu](mailto:lauren.larochelle@unh.edu)

Health Law and Policy Senior Associate  
Institute for Health Policy and Practice

# Acknowledgment

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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.



# Lucy C. Hodder

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Director of Health Law and Policy  
Professor, UNH Franklin Pierce School of Law  
Institute for Health Policy and Practice  
[Lucy.Hodder@unh.edu](mailto:Lucy.Hodder@unh.edu)

Lucy Hodder is the Director of Health Law and Policy Programs at the University of New Hampshire College of Health and Human Services, Institute for Health Policy and Practice, and Professor of Law at UNH Franklin Pierce School of Law. She developed and oversees the Certificate in Health Law and Policy program for law students and teaches a variety of health law courses. Lucy's research addresses the health care payment and delivery system reform, and her projects focus on developing strategies for sustainable and patient centered systems.

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.



# Lauren LaRochelle

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Health Law & Policy Senior Associate  
UNH Institute for Health Policy and Practice  
[Lauren.LaRochelle@unh.edu](mailto:Lauren.LaRochelle@unh.edu)

Lauren LaRochelle joined the Institute for Health Policy and Practice as a Health Law and Policy Senior Associate in January 2019. Lauren provides support across various projects in the Health Law and Policy focal group. Prior to joining IHPP, she served as an Assistant Attorney General in the Office of the Maine Attorney General advising various professional licensing boards. She also clerked for the Maine Supreme Judicial Court.



# 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

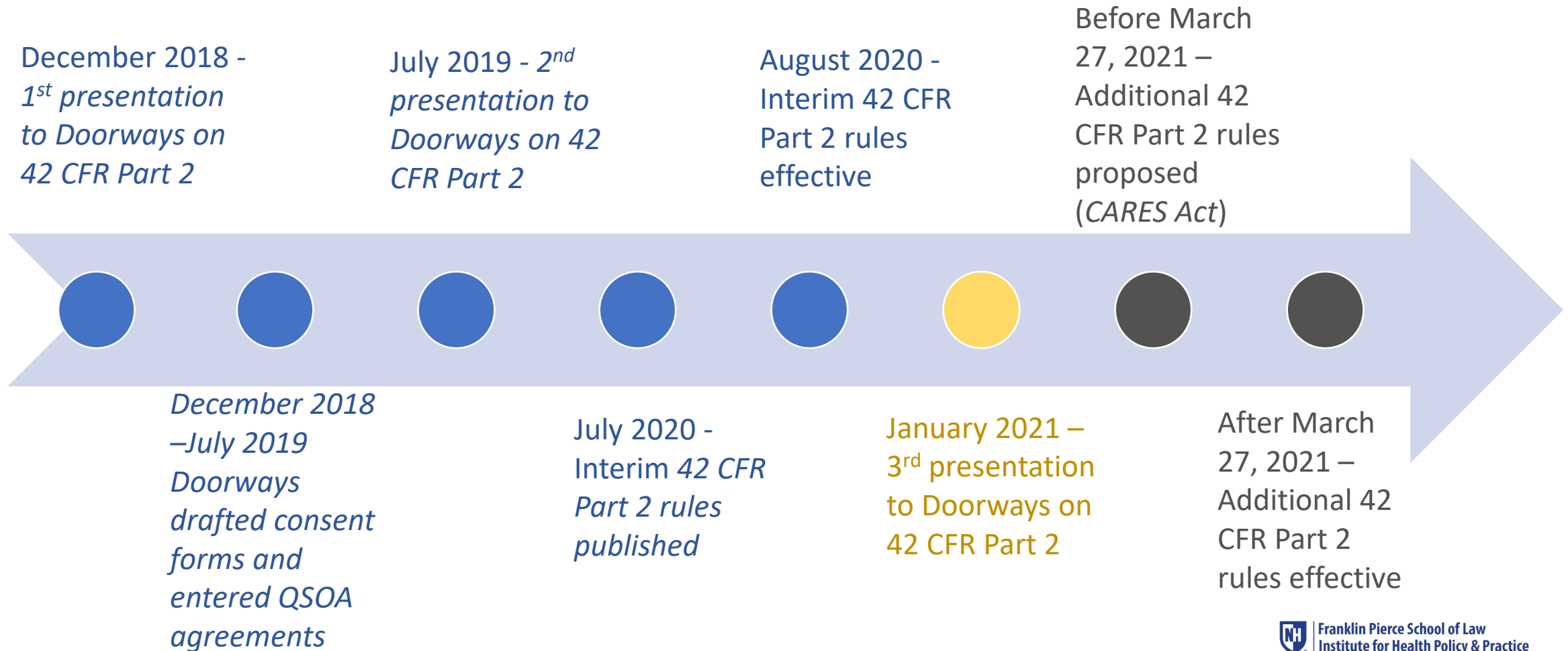
Tips

# 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

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# Access and Transparency Developments

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**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

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# Potential Sources of Confidentiality/Privacy Restrictions

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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

Jurisdiction	Statute or Regulation	Scope
Federal	HIPAA Privacy Rules	Protects individually identifiable health information maintained by providers, payers and their contractors from disclosure. Heightened protections for psychotherapy notes.
	42 CFR Part 2	Protects the confidentiality of substance abuse patient records from disclosure without express patient consent.
	FERPA	Protects education records
New Hampshire	RSA 332-1:1	Medical information in the medical records in the possession of any health care provider shall be deemed to be the property of the patient
	RSA 318-B:12-a	Protects reports and records of treatment of minors for drug dependency as confidential
	RSA 330-A:32	Protects communications between mental health practitioners and patients as privileged
	RSA 330-C:26	Protects information held by a licensed alcohol or other drug use professional performing substance use counseling services unless permitted by 42 CFR Part 2
	RSA 135-C:19-a	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



## Remind Me – Is there a difference between HIPAA and Part 2?

### HIPAA

HHS

**Applies to** covered entities (healthcare providers, health plans, healthcare clearinghouses) and Business Associates

**Protects:** privacy and security of general health information

**Purpose:** to protect health data integrity, confidentiality, and accessibility

**Permits** disclosures *without* patient consent for treatment, payment and healthcare operations and for public health purposes.

### 42 CFR Part 2

SAMHSA

**Applies to** SUD patient records from federally-assisted “Part 2 programs”

**Protects:** privacy and security of records identifying individual as seeking/receiving Substance Use Disorder (SUD) treatment

**Purpose:** to encourage people to seek Substance Use Disorder (SUD) treatment and reduce stigma through enhanced confidentiality

**Prohibits disclosures except with** a patient consent for treatment, payment, and healthcare operations, with limited exceptions

# Confidentiality Provisions in the Doorway Contracts

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**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

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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”

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## Who is a Part 2 Patient?

A **Part 2 patient** 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.

## What is Treatment?

“**Treatment**” 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.

## 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

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# Part 2 Requirements – Check List

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- 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

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# Security Policies (2.16)

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- 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.

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# Notice to Patients at time of admission to the Part 2 Program (2.22)

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## ***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

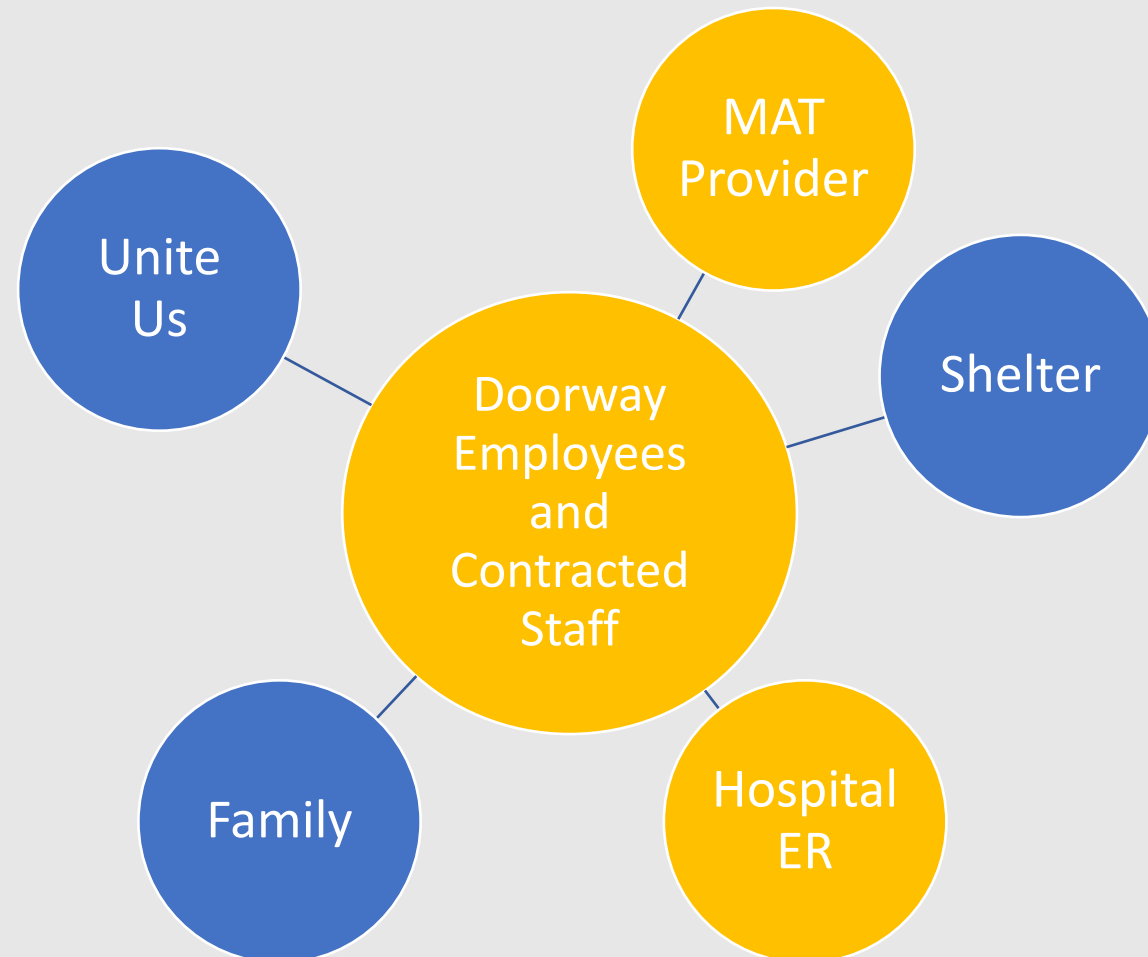
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# Non-Redisclosure Warning: When are disclosures made?

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# Non-Disclosure Notice – **NEW**

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

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## OPTION 1 – long version

**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.”

## OPTION 2 – short version

**“42 CFR part 2 prohibits unauthorized disclosure of these records”**

# Part 2 Requirements – Details

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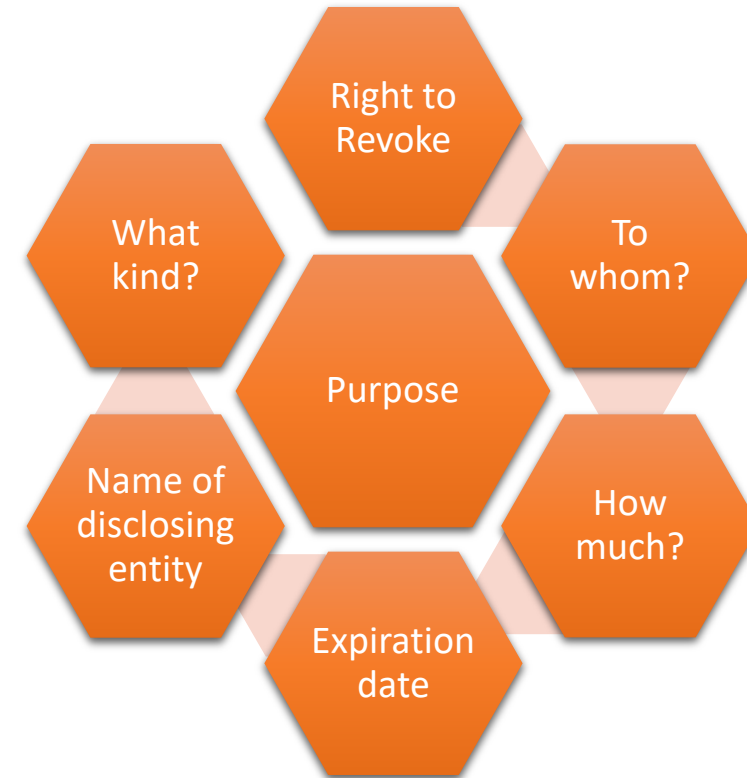
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# Patient Consent: Elements (2.31)

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- 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...**NEW**

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To  
Whom

2021

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

...to whom disclosure will be made.

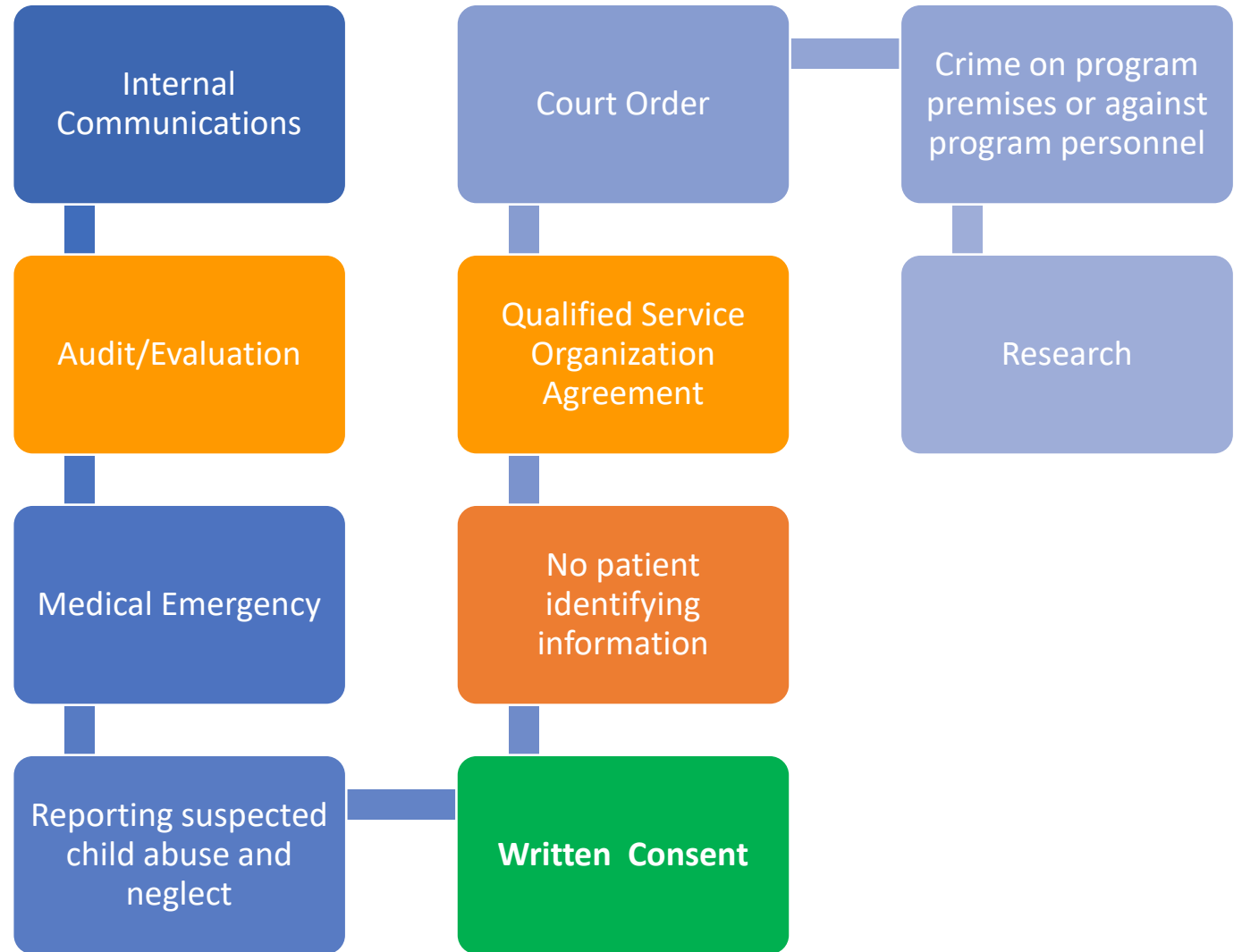
# Exceptions to 42 CFR Part 2's Prohibition on Disclosure of SUD Information

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# When Can Part 2 Records be Shared?

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# Part 2

# Exception

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## Qualified Service Organization Agreement

# Exception: Qualified Service Organization (2.12(c)(4))

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- 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

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# Part 2

# Exception

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Audit/Evaluation

# Audit and Evaluation Exception

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## **Audits when for compliance with rules, laws, policies 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

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# Key updates for the current moment!

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- 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

Record 2.11	Applicability 2.12(d)(2)(ii)	Consents (2.31)	Consents for payment and health care operations	PDMP
Definition Change to Facilitate Care Coordination	Change to Facilitate Care Coordination	“To Whom” Simplified	Agents and administration made easier	Outpatient Treatment Providers
<p>Excludes information conveyed orally to a non-Part 2 provider for treatment purposes with a patient consent even if written down.</p> <p>Means resulting medical record is not covered by Part 2</p>	<p>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.</p> <p>Part 2 records received by the non-Part 2 treating provider should be segmented, however.</p>	<p><b>General requirement for designating recipients:</b></p> <p>Allows patients to name a <b>person</b> or <b>entity</b> to which a disclosure can be made</p> <p>Consent form no longer has to name a specific person at a non-treating entity.</p> <p>“to Housing Finance Authority”</p>	<p>A patient consent to another entity generally for “payment and health care operations” allows entity and agents to use Part 2 information as necessary for 18 different activities.</p> <p>Activities include “care coordination and/or case management services in support of payment or health care operations.”</p>	<p>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.</p> <p>Allows a treating provider to check a central registry to confirm the appropriateness of prescribed therapy.</p>

# Payment and Health Care Operations by Consent

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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

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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.**

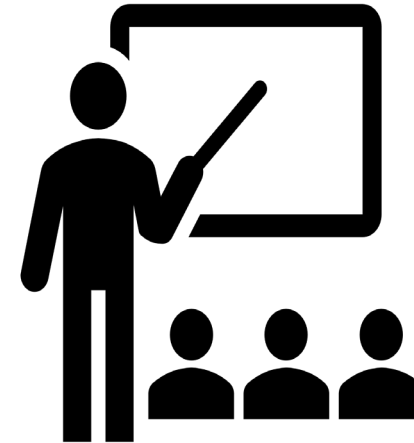
# Doorway Practice Tip

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- 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

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# CARES Act and Part 2

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42 U.S.C. § 290dd-2 is the statutory basis for 42 C.F.R. Part 2. The Federal Coronavirus Aid, Relief, and Economic Security (CARES) Act, signed March 27, 2020, amends 42 U.S.C. § 290dd-2 to align more closely with HIPAA privacy rules.

The Final Part 2 rules were intended to facilitate well-coordinated care for patients with SUD



# CARES Act Changes – 42 USC 290dd-2

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- 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

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WAIT FOR PROPOSED  
RULES



COMMENT ON PROPOSED  
RULES

# Next Up – Session 2

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Consents, telehealth,  
emergencies



Answer questions and  
hypos



Apply standards

# Resources

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<https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf>

<https://www.samhsa.gov/sites/default/files/how-do-i-exchange-part2.pdf>

[Notice Prohibiting Redisclosure](#)

[https://nahic.ucsf.edu/wp-content/uploads/2019/01/New-Hampshire-AYAH-Confidentiality-Guide\\_Final.pdf](https://nahic.ucsf.edu/wp-content/uploads/2019/01/New-Hampshire-AYAH-Confidentiality-Guide_Final.pdf)

# Questions?

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# Appendix

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



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# Summary of Final Rule Changes

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**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.

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**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