

**Regulatory Compliance Updates for
Behavioral Health Providers**



**BH Summit December 2024
What's New – What's Changed?**

Lucy C. Hodder, JD
Lucy.Hodder@unh.edu
Director, Health Law and Policy
Distinguished Visiting Professor
UNH Franklin Pierce School of Law

Laurie Beth Pliakos, JD
Lauriebeth.Pliakos@nstride.health
Chief Compliance Officer & General Counsel
InStride Health
Adjunct Professor of Health Law
UWV Franklin Pierce School of Law



Lucy C. Hodder

Director of Health Law and Policy
Distinguished Visiting Professor of Law
UNH Franklin Pierce School of Law
Institute for Health Policy and Practice, Consultant
Lucy.Hodder@unh.edu

Lucy Hodder is the Director of Health and Life Sciences Law and Policy Programs at the University of New Hampshire Franklin Pierce School of Law and serves as a Distinguished Visiting Professor 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 advisors, 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 Figurali, 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.



Laurie Beth Pliakos

Laurie Beth has devoted her career to improving healthcare accessibility, quality, and privacy. A regulatory attorney and compliance professional, she has provided legal counsel to a wide range of healthcare providers, including academic medical centers and acute care hospitals, physician groups, home health agencies, and state vaccine associations.

Currently, Laurie Beth serves as Chief Compliance Officer & General Counsel at InStride Health, an outpatient provider specializing in anxiety and ODD treatment for pediatric and young adult patients across ten states. She previously worked as in-house counsel at Catholic Medical Center, where she focused on regulatory and corporate legal matters. Laurie Beth also practiced law at the law firm of Hinckley Allen in its Healthcare Practice Group, and was in-house counsel at Kildare, an organization that administers state universal vaccine funding programs.

In addition to her legal work, Laurie Beth has taught Health Law at the University of New Hampshire Franklin Pierce School of Law since 2019.

Chief Compliance Officer & General Counsel
InStride Health
Adjunct Professor of Health Law
UNH Franklin Pierce School of Law
Lauriebeth.Pliakos@nstride.health

Disclaimer

This presentation is for educational purposes only, is not legal advice, and is not intended to create an attorney-client relationship.



Goals for Today

- 1 Confidentiality Primer
- 2 New Rules
- 3 Hypotheticals
- 4 Emerging Issues to Watch: Telehealth Practice & Consent

Many Privacy and Confidentiality Laws Apply to Behavioral Health Practice

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 use disorder 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) (i.e. patients with SMI)



© 2023 Institute for Health Policy and Practice, LPPH. All Rights Reserved.

HIPAA General Rule

The Health Insurance Portability and Accountability Act (HIPAA) regulations protect the privacy of protected health information (PHI) created or received by healthcare providers, health plans, and healthcare clearinghouses.

HIPAA seeks to protect and enhance patient rights by controlling inappropriate uses and disclosures of information and giving patients access to their health information.

© 2023 Institute for Health Policy and Practice, UNH. All Rights Reserved.

Franklin Pierce School of Law
Institute for Health Policy & Practice
Health Law & Policy

2024 Rule Changes – Now What?

Franklin Pierce School of Law
Institute for Health Policy & Practice
Health Law & Policy

Where Did These New Rules Come From?

- Issued by the U.S. Department of Health and Human Services, Office for Civil Rights in April of 2024
- Key Dates:
 - Effective Date: June 25, 2024
 - General Compliance Date: December 23, 2024
 - Compliance Date for Updates to Notice of Privacy Practices: February 16, 2026

Franklin Pierce School of Law
Institute for Health Policy & Practice
Health Law & Policy

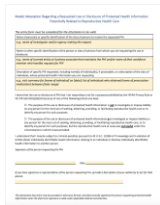
What's New? 3 Requirements to Support Reproductive Health Care Privacy:

1. **(NEW) Prohibited Activities:** HIPAA regulated entities cannot use or disclose PHI:
 - To **investigate** or **impose liability** on any person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care;
 - To **identify** any person for either of the purposes above.



What's New? 3 Requirements to Support Reproductive Health Care Privacy:

2. **(NEW) Attestation Requirement:** HIPAA regulated entities must obtain an **attestation from a person requesting information** before using or disclosing PHI about reproductive health care to health oversight agencies, law enforcement, coroners/medical examiners, or in judicial or administrative proceedings.



<https://www.hhs.gov/sites/default/files/model-attestation.pdf>



What's New? 3 Requirements to Support Reproductive Health Care Privacy:

3. **(NEW) Update to Notice of Privacy Practices (NPP):** HIPAA covered entities must update their NPPs to (i) state that they will not engage in Prohibited Activities, with examples, and (ii) explain the activities that would require attestation forms, with examples.



What's New? Clarification about Personal Representatives:



- **Personal Representatives** are people who have legal authority to make health care decisions for another (e.g., parent of a minor, legal guardian, etc.)
- A covered entity can choose not to recognize a personal representative if the person has or may commit domestic violence, abuse, or neglect against the patient.
- **(NEW)** OCR clarified that it is not reasonable to decline to recognize a personal representative simply because they facilitated reproductive health care for the patient.

Georgetown University School of Law
Institute for Health Policy & Practice
Health Law & Policy

Compliance Update Check List

1. Review your organization's medical record use and disclosure policies and procedures.
2. By December 23, 2024, update policies and procedures to ensure prohibited activities are not performed, and to require attestations where appropriate.
3. Train staff on prohibited activities and attestation process by December 23, 2024.
4. Update NPP to explain prohibited activities and attestation process by February 16, 2026.



Georgetown University School of Law
Institute for Health Policy & Practice
Health Law & Policy

Hypothetical

Georgetown University School of Law
Institute for Health Policy & Practice
Health Law & Policy

Hypo 1: Kathy

You provide mental health services in an OB/GYN clinic. A family attorney in Texas sends your practice a subpoena demanding medical records for one of your patients, Kathy. Kathy recently separated from her partner and moved from Texas to New Hampshire. She was pregnant when she arrived in New Hampshire, but recently experienced a miscarriage.

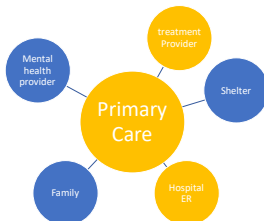
Can you release the records?

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)

With limited exceptions, 42 CFR Part 2 requires patient consent for disclosures by covered entities of protected health information even for the purposes of treatment, payment, or health care operations.

Sharing Information while protecting privacy along the continuum of care



What Makes Part 2 Program Records Different?



Heightened protections against access by law enforcement and criminal legal system



Requirements for written consent to disclose (generally) from a Part 2 Program

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).



Franklin Pierce School of Law
Institute for Health Policy & Practice
Health Law & Policy

2024 Rule Changes – Now What?

Franklin Pierce School of Law
Institute for Health Policy & Practice
Health Law & Policy

Where Did These New Rules Come From?

- Implement changes required by the CARES Act (2020)
- Align Part 2 with HIPAA – *kinda!*
- Key Dates:
 - Effective: April 16, 2024
 - Compliance Date: February 16, 2026
- Anti-discrimination rulemaking still in process prohibiting use of Part 2 records to discriminate against a patient in healthcare, employment, housing, access to courts, social services and benefits.



Where Are You In Your Compliance Journey?

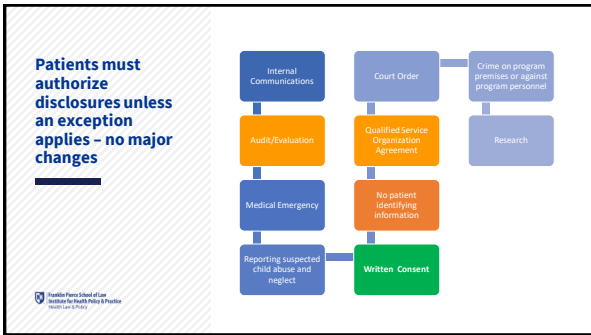
1. I had no idea there were new rules around SUD treatment record confidentiality?
2. I know there are new rules but haven't reviewed them yet.
3. I am just learning the basics!
4. I have reviewed and begun to implement a compliance plan.
5. My organization is already in compliance, and my staff is fully trained.

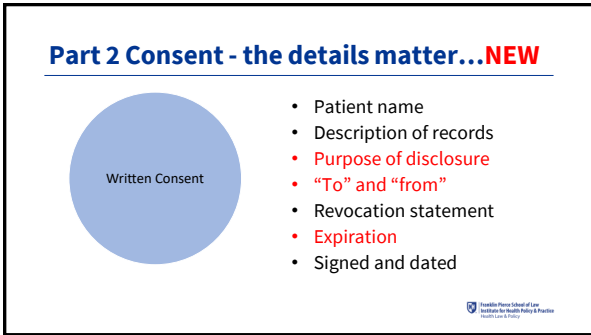


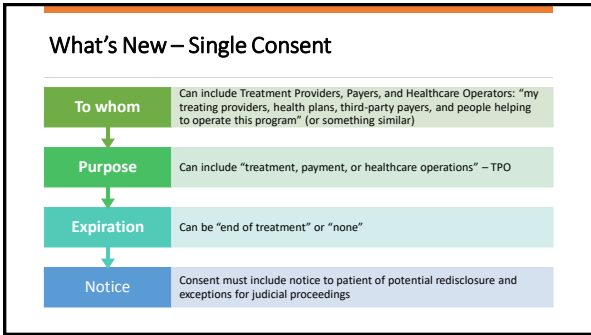
Compliance Update Check List

1. Part 2 remains stricter than HIPAA.
2. HIPAA privacy notices can include Part 2 notice.
3. Written consents should be updated to clarify disclosure will include for "treatment, payment, and healthcare operations."
4. Know the requirements against disclosure for criminal investigations.
5. Provider may specially protect SUD counseling notes.
6. New breach notification rules.
7. New complaint process, penalties, and enforcement.









What Can Part 2 Program Do with Records?

If consent signed, can disclose for TPO

Recipients and Business Associates can further disclose in accordance with HIPAA

- Except for any proceedings against patient

Subsequent disclosures lose Part 2 protections

Hypotheticals

Focus: PHI – Center of Excellence for PHI
July 17, 2024 Webinar – lightly updated and edited

Healthcare Privacy School of Law
Institute for Health Policy & Practice
Washington, DC

Hypo 2: Disclosures (Frances)

- Frances is referred by her primary care physician to a recovery center called "Recovery for Life."
- When she visits the program for evaluation and treatment, she signs a consent form authorizing uses and disclosures of her records:
"To my treating providers, third party insurance plans, and people operating this program for treatment, payment, and healthcare operations."

Healthcare Privacy School of Law
Institute for Health Policy & Practice
Washington, DC

Question: Which of the Following Disclosures are Permitted by Recovery for Life?

- 1) Frances's treatment provider at Recovery for Life can share all of Frances's records with the treatment team and other providers at Recovery for Life.
- 2) Recovery for Life can share all of Frances's records with her primary care physician.
- 3) Recovery for Life can respond to a question from the emergency department at the local hospital when Frances is admitted.
- 4) Recovery for Life can bill Frances's insurance company for reimbursement and respond to prior authorization requests with treatment information.
- 5) Recovery for Life can provide Frances's information to the County Attorney's Office in response to a subpoena.



Question: Which of the Following Disclosures are Permitted by Frances's PCP?

Frances's primary care physician, Dr. Caregiver, receives records from Recovery for Life in order to follow-up on Frances's recovery. How can the primary care practice can use or disclose Frances' records?

- 1) The PCP can engage in any use permitted by HIPAA. For example, Dr. Caregiver can share records with Frances's cardiologist in another practice.
- 2) The PCP can disclose to Frances's health insurance plan to obtain payment for treatment after a retroactive denial of coverage.
- 3) The PCP can disclose to the Division of Public Health as part of a federally funded grant program, if the records are de-identified, consistent with HIPAA regulations.
- 4) The PCP can disclose to its consultant engaging in a compliance review



Question: What about a third-party request?

What if the Division for Children, Youth, and Families (DCYF) requests Frances's records from Recovery for Life, Dr. Caregiver at the primary care practice, and Frances's cardiologist in relation to pending termination of parental rights proceedings? Who can release Frances's treatment records in response to the request?

- 1) Recovery for Life?
- 2) Dr. Caregiver?
- 3) The Cardiologist?



Answer: It Depends

Recovery for Life: Frances's records are protected by 42 CFR Part 2. A **court order** or **specific written consent** is still required.

Dr. Caregiver (who received records from Recovery for Life): Frances's records can be used and shared, consistent with HIPAA, **except for legal proceedings against Frances.**

Cardiology Practice (which received records from Dr. Caregiver): Frances's records are no longer protected by 42 CFR Part 2. Disclosure can be made consistent with HIPAA.



Hypo 3: Treating Provider Relationships (Claire)

Claire calls and makes an appointment with a SUD treatment provider to come in for an assessment. Claire has not yet come in for her appointment.

Is Claire's identity protected by 42 CFR Part 2?

Quoted from the Legal Action Center Presentation, "42 CFR Part 2: What Changed in the Amendments" p 43 (Mar. 6, 2018)



Answer: Yes

Yes. The SUD provider has a "treating provider" relationship with Claire, so 42 CFR Part 2 protects Claire's identity.

- By making an appointment, Claire agreed to be assessed and diagnosed for a condition (it does not matter what type of condition).
- By scheduling Claire for an appointment, the SUD provider agreed to undertake the assessment of her.
- Remember, an in-person encounter is not required to establish a treating provider relationship.

Quoted from the Legal Action Center Presentation, "42 CFR Part 2: What Changed in the Amendments" p 43 (Mar. 6, 2018), with edits



Hypo 4: New Consent Form Requirements – Entity (Alison)

Alison wants her Part 2 program to coordinate transportation to, and supports from, Housing Helpers. She signs a consent form authorizing certain information to be disclosed to "Housing Helpers."

Is this permissible?

Quoted from the Legal Action Center Presentation, "Confidentiality & Communication of SUD Treatment Records: 42 CFR Part 2 and HIPAA" p 70 (Dec. 12, 2018 – Segment A), with edits



Answer: Consent Form Requirements

Yes!

Alison may consent to disclosure of her Part 2 treatment records to an entity (here, the housing service coordinators) without naming a specific person as the recipient for the disclosure.

Modified from the Legal Action Center Presentation, "Confidentiality & Communication of SUD Treatment Records: 42 CFR Part 2 and HIPAA" p 70 (Dec. 12, 2018 – Segment A)



Communications during a Medical Emergency

Can the Part 2 "medical emergency" exception be invoked to head off a potential medical emergency such as a potential drug interaction?

From SAMHSA FAQs Q 9 <https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs>



Communications during a Medical Emergency

If a health care provider treating an individual determines that a medical emergency exists as defined in Part 2, i.e., "a condition which poses an immediate threat to the health of any individual [not just the patient], and which requires immediate medical intervention," and in treating the medical emergency the health care provider needs information about potential drug interactions, then that information and any other information contained in the Part 2 record that the treating health care provider determines he or she needs to treat the medical emergency can be disclosed. If no such determination exists, SAMHSA recommends trying to obtain consent from the patient.

It should be noted that concern alone about potential drug interaction may not be sufficient to meet the standard of a medical emergency. Thus, based on the circumstances of the presenting situation, SAMHSA recommends that health care providers should obtain consent from the patient where feasible.

From SAMHSA FAQs Q 9 <https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs>





Does Part 2 prohibit one Social Service Agency from sharing information with another Social Service Agency?

No!

© 2021 Institute for Health Policy and Practice, UPenn. All Rights Reserved.



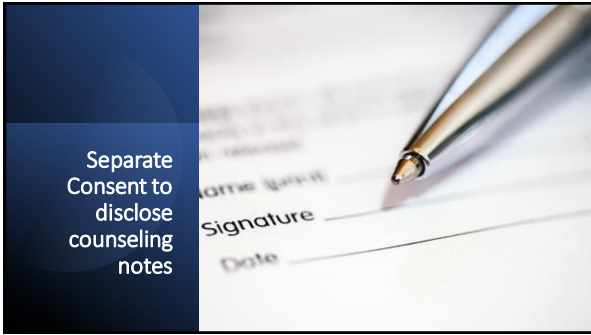
Counseling Notes

• New definition in § 2.11:

Substance use disorder (SUD) counseling notes means notes recorded (in any medium) by a part 2 program provider who is a SUD or mental health professional documenting or analyzing the contents of conversation during a private SUD counseling session or a group, joint, or family SUD counseling session and that are separated from the rest of the patient's SUD and medical record.

SUD counseling notes excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.





Other Points to Remember

1. Notice of 42 CFR Part 2 can be combined with HIPAA notice
2. Disclosures must be made with short or long form of notice
3. Conditioning treatment on TPO consent discouraged
4. Accounting for disclosures
5. Complaints
6. Breach Notification

Franklin Pierce School of Law
Institute for Health Policy & Practice
Franklin Pierce University



Key Points: Part 2 and Telehealth

Written consent is required to share Part 2 information, even for remote services.

As before, no consent is required in a medical emergency, but SAMHSA has given providers more discretion.

E-signatures and photocopied signatures are okay if state law does not prohibit.

Quoted from the Legal Action Center Presentation, "Privacy Considerations for Telehealth During COVID-19" (January 19, 2021)

Franklin Pierce School of Law
Institute for Health Policy & Practice
Franklin Pierce University

Telehealth Licensing General Rule

Typically, the **patient's** location is the "place of service" during at telehealth encounter. Therefore, clinicians need to be licensed or otherwise authorized to practice wherever the patient is located.

Licensing Compacts are bringing more flexibility to telehealth practice (e.g., Interstate Medical Licensure Compact (IMLC), Psychology Interjurisdictional Compact (PSYPACT), Social Work Interstate Licensing Compact)

© 2023 Institute for Health Policy and Practice, UNH. All Rights Reserved.



Understand the Difference Between Licensing Authority and Credentialing

- **Can you practice without a state license** if a state licensing compact law permits it?
 - Yes, you can practice in accordance with the state's licensing compact law.

But this is different from:

- **Can you get paid for it?**
 - Maybe not. Some insurance companies do not recognize licensing compacts for purposes of credentialing.
- Similarly, just because a provider is **credentialed** with a national payor, that does not mean the provider is **legally authorized** to practice everywhere that the payor operates. State licensing laws still apply!



Consent General Rule

Informed consent is a legal and ethical requirement for treatment.

With some exceptions, typically informed consent must be given by a patient who is 18 or older. Consent can also be given by a person with legal decision-making authority if the patient is unable to provide consent due to age or incapacity.

© 2023 Institute for Health Policy and Practice, UNH. All Rights Reserved.



2024 Rule Changes – Now What?

 Franklin Pierce School of Law
Institute for Health Policy & Practice
Health Law & Policy

Nothing is Changing - YET

- 2023: NH considered a bill (SB 184) that would have allowed minors to consent to their own mental health treatment starting at age 16. It did not pass.
- 2024: SB 573-FN became law, establishing a committee to study consent and confidentiality laws applicable to adolescent and young adult health care in NH.

 Franklin Pierce School of Law
Institute for Health Policy & Practice
Health Law & Policy



Questions?

 Franklin Pierce School of Law
Institute for Health Policy & Practice
Health Law & Policy

© 2023 Institute for Health Policy and Practice, UNH. All Rights Reserved.
