

The Latest Federal Health Privacy Regulations: Explaining the New Substance Use Disorder Patient Records and HIPAA Final Rules

Health Law Webinar

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Fredrikson

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Agenda

- Quick Federal Privacy Overview
- Part 2 Updates
- HIPAA Updates

Overview of Federal Healthcare Privacy Laws

Health Insurance Portability and Accountability Act (“HIPAA”)	42 CFR Part 2 (“Part 2”)	FTC’s Health Breach Notification Rule (“HBNR”)
1996 (Statute); 2005 (Regulations)	1970 (First SUD Statute); 1975 (Regulations)	2009 (Statute and Regulations)
Applies to Covered Entities and Business Associates Overlaps with Part 2	Applies to Part 2 Programs, QSOs, and Lawful Holders Overlaps with HIPAA	Applies to vendors of personal health records and related entities Does <u>not</u> apply to HIPAA Covered Entities and Business Associates
Privacy Rule, Security Rule and Breach Notification Rule	Restrictions on Uses and Disclosures; Notice Requirements; Breach Notification Rule	Breach notification requirements
Protected Health Information	SUD patient records	Personal Health Records

Background on 42 CFR Part 2

- Protects the confidentiality of substance use disorder (SUD) treatment records.
- Designed to help address concerns that discrimination and fear of prosecution deter people from entering treatment for SUD.
- Applies heightened or extra protections for SUD records, particularly with respect to law enforcement disclosures.
- Applies to Part 2 Programs and Qualified Service Organizations (QSOs).

Part 2 Programs

- Part 2 Program means a **federally-assisted**:
 - Person (other than a general medical facility) that **holds itself out** as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or
 - An identified unit within a general medical facility that **holds itself out** as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or
 - Medical personnel or other staff in a general medical facility whose **primary function** is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.
- “Federally assisted” encompasses a broad set of activities, including management by a federal office or agency, receipt of any federal funding, or registration to dispense controlled substances related to the treatment of SUDs.
- “Holds itself out” means any activity that would lead one to reasonably conclude that the individual or entity provides SUD diagnosis, treatment, or referral for treatment.

Long-Awaited Final Rule

- Implements Section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (enacted March 27, 2020).
- Requires HHS to align certain aspects of Part 2 with HIPAA and update Notice of Privacy Practices requirements to address Part 2 protections and individual rights.
- “Increase alignment with HIPAA...improve workability and decrease burdens on programs, covered entities and business associates.”

Part 2 – Key Terms Refresher/Updates

- **Lawful Holder** is a person who is bound by this part because they have received records as the result of one of the following: (1) written consent in accordance with § 2.31 with an accompanying notice of disclosure; or (2) one of the exceptions to the written consent requirements in 42 U.S.C. 290dd-2 or this part.
- **Qualified Service Organization (QSO)** is a person who:
 - (1) provides services to a part 2 program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, population health management, medical staffing, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and
 - (2) Has entered into a written agreement with a part 2 program under which that person: (i) Acknowledges that in receiving, storing, processing, or otherwise dealing with any patient records from the part 2 program, it is fully bound by the regulations in this part; and (ii) If necessary, will resist in judicial proceedings any efforts to obtain access to patient identifying information related to substance use disorder diagnosis, treatment, or referral for treatment except as permitted by the regulations in this part.
 - (3) **QSO** includes a person who meets the definition of *business associate* in [45 CFR 160.103](#), paragraphs (1), (2), and (3), for a part 2 program that is also a covered entity, with respect to the use and disclosure of protected health information that also constitutes a “record” as defined by this section.

Part 2 – Key Terms Refresher/Updates

- **Records** means any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient (e.g., diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts), and including patient identifying information, provided, however, that information conveyed orally by a part 2 program to a provider who is not subject to this part for treatment purposes with the consent of the patient does not become a record subject to this part in the possession of the provider who is not subject to this part merely because that information is reduced to writing by that provider who is not subject to this part. Records otherwise transmitted by a part 2 program to a provider who is not subject to this part retain their characteristic as records in the hands of the provider who is not subject to this part, but may be segregated by that provider.
- **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.

Patient Consent

- More closely aligns required elements with a HIPAA authorization.
- Recipients: Names or “class of persons.”
- Special requirements for recipient entities are “intermediaries.”
- *Intermediary* means a person, other than a part 2 program, covered entity, or business associate, who has received records under a general designation in a written patient consent to be disclosed to one or more of its member participant(s) who has a treating provider relationship with the patient.

Single Consent for Future TPO Uses

- A patient may provide a **single consent** for all future uses and disclosures for treatment, payment and healthcare operations (“TPO”).
- A Part 2 program may condition a patient’s treatment on the patient signing such a general consent for TPO (though treatment may not be conditioned on consent for a use or disclosure of SUD counseling notes, which are subject to more stringent requirements).
- Recipients: “[M]y treating providers, health plans, third-party payers, and people helping to operate this program.”
- “People helping to operate this program” could include case management and care coordination providers.

TPO Disclosures

- If the recipient is a covered entity or business associate to whom a record (or information contained in a record) is disclosed for purposes of treatment, payment, or health care operations, a written consent must include the statement that the patient's record (or information contained in the record) may be redisclosed in accordance with the permissions contained in the HIPAA regulations, except for uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient.

SUD Counseling Notes

- Creates a new definition for an SUD clinician's notes analyzing the conversation in an SUD counseling session that the clinician voluntarily maintains separately from the rest of the patient's SUD treatment and medical record and that require specific consent from an individual and cannot be used or disclosed based on a broad TPO consent.
- Analogous to protections in HIPAA for psychotherapy notes.

Patient Consent

- Prohibits combining patient consent for the use and disclosure of records for civil, criminal, administrative, or legislative proceedings with patient consent for any other use or disclosure.
- Requires a separate patient consent for the use and disclosure of SUD counseling notes.
- Requires that each disclosure made with patient consent include a copy of the consent or a clear explanation of the scope of the consent.

Redisclosure Rights

- When Part 2 records are disclosed for **TPO** to a **covered entity or business associate**, the recipient may further disclose those records in accordance with HIPAA, except for uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient.
- When Part 2 records are disclosed with consent given once for all future **TPO** to a Part 2 program that is **not a covered entity or business associate**, the recipient may further disclose those records consistent with the consent.
- When Part 2 records are disclosed for **payment or health care operations activities** to a **lawful holder that is not a covered entity or business associate**, the recipient may further disclose those records as may be necessary for its contractors, subcontractors, or legal representatives to carry out the payment or health care operations specified in the consent on behalf of such lawful holder.
- These relaxed redisclosure rules only apply to the recipient of Part 2 records. As such, a Part 2 program that obtains patient consent for TPO is limited to using or disclosing Part 2 records for TPO in accordance with the consent.

Other “Flexibilities”

- Adds an express statement that segregating or segmenting Part 2 records is not required.
- “A part 2 program, covered entity, or business associate that receives records based on a single consent for all treatment, payment, and health care operations is not required to segregate or segment such records.” § 2.12(d)(2)(i)(C).
- Does not apply to SUD Counseling Notes.

Other Uses and Disclosures

- Most are permissive and not mandatory.
- Permits disclosure of records without patient consent to public health authorities, provided that the records disclosed are de-identified according to the standards established in the HIPAA Privacy Rule.
- Restricts the use of records and testimony in civil, criminal, administrative, and legislative proceedings against patients, absent patient consent or a court order.

Penalties

- Old: Part 2 violators were subject only to potential criminal penalties and enforcement by the Department of Justice (“DOJ”).
- New:
 - The Final Rule aligns Part 2’s enforcement framework with that of HIPAA’s so that violators of Part 2 will now be subject to the same potential civil and criminal penalties as covered entities and business associates for HIPAA violations.
 - DOJ will continue to have enforcement authority for criminal penalties and state attorneys general may bring civil suits on behalf of state residents.

Breach Notification and Policies

- The Final Rule makes the HIPAA Breach Notification Rule applicable to Part 2 programs that experience breaches of unsecured Part 2 records.
- “Unsecured records” = “unsecured protected health information”
- De-identification concept mirrored.
- Policy exception for family, friends, and other informal caregivers who are lawful holders.

Lawful Holders

- Adds definition.
- Allows patients to file complaints against both Programs and Lawful Holders. (2.4)
- Clarifies downstream recipients from a lawful holder continue to be bound by the prohibition on use of a patient's records in proceedings against the patient, absent written consent or a court order. (2.12(d)).
- Requires lawful holders to have a written contract (with required provisions) before redisclosing records to contractors or subcontractors. (2.33(b)(3) and (c)).
- This section also provides that when records are disclosed for payment or health care operations activities to a lawful holder that is not a covered entity, business associate, or part 2 program, the recipient may further use or disclose those records as may be necessary for its contractors, subcontractors, or legal representatives to carry out the payment or health care operations specified in the consent on behalf of such lawful holders.

Patient Notice § 2.22

- Enhance and restructured Part 2 patient notice requirements to align with HIPAA.
- Must include the patient's right to:
 - A list of disclosures by an intermediary for the past 3 years as provided in § 2.24; and
 - Elect not to receive any fundraising communications to fundraise for the benefit of the part 2 program.
- Single/joint notice is fine for dually-regulated entities.
- Acknowledged burden, but believe this is offset by “decreased number of consents required.”
- HIPAA NPP updates will come in separate rulemaking.

Safe Harbor

- Creates a limit on civil or criminal liability for uses or disclosures inconsistent with Part 2 by individuals acting on behalf of an investigative agency when:
 - Acting within the scope of their employment in the course of the investigation or prosecuting a Part 2 program or person holding the record; and
 - Acting with **reasonable diligence** to determine whether a provider is subject to Part 2 before making a demand for records in the course of an investigation.
- Only applicable in instances where records are obtained for the purposes of investigating a part 2 program or person holding the record, not a patient.

Compliance Timelines

- Final Rule Effective Date: April 16, 2024
- Compliance Date: February 16, 2026
- “[P]ersons who are subject to the regulation and are able to voluntarily comply with regulatory provisions finalized in this rulemaking may do so at any time after the effective date.”

HIPAA Privacy Rule to Support Reproductive Health Care Privacy



Applies to All Covered Entities and Business Associates

- Very broad definitions and applicability rules.
- Applies to information you have even if you did not provide the care.
- All NPPs must change.
- Many BAAs must change.
- HHS is clear: Applies to everyone

Technical Details

- 89 Fed. Reg. 32976.
- Amendments to:
 - 45 C.F.R. § 160.103.
 - 45 C.F.R. § 164.502, .509, .512, .520, .535.
- Final Rule issued April 26, 2024.
- Effective date: June 25, 2024.
- Compliance Dates:
 - Most issues: **December 23, 2024.**
 - NPP provisions in 45 C.F.R. § 164.520: February 16, 2026.
 - *Aligning with changes to Part 2 NPP changes.*

Creates Definition of “Reproductive Health Care”

- Will be codified in 45 C.F.R. § 160.103.
- “health care . . . that affects the health of an individual in **all matters relating to the reproductive system and to its functions and processes**. This definition shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care”
- Broad Definition.

Broad Applicability

- Generally, the rules apply to information related to “seeking, obtaining, providing, or facilitating reproductive health care”
- 45 C.F.R. § 164.502 creates a further broad application of “seeking, obtaining, providing, or facilitating” to non-exhaustive list:
 - “expressing interest in, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, administering, authorizing, providing coverage for, approving, counseling about, assisting, or otherwise taking action to engage in reproductive health care; or attempting any of the same”
- Attestation requirement: “potentially related to”

Prohibited Disclosures Related to Reproductive Health Care

- Adds a **prohibited** use or disclosure to 45 C.F.R. § 164.502.
- Covered Entity/Business Associate may not use or disclose PHI for any of the following activities:
 - (1) “To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.”
 - (2) “To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.”
 - (3) To identify any person for any of the above purposes.

Prohibited Disclosures Related to Reproductive Health Care (con.): Rule of Applicability

- Rule of Applicability limits the rule to only apply where the covered entity/BA that received the request “reasonably determined”:
 - (1) “The reproductive health care is **lawful under the law of the state in which such health care is provided** under the circumstances in which it is provided.”
 - (2) “The reproductive health care is **protected, required, or authorized by Federal law**, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided.”
 - (3) The presumption applies . . .

Prohibited Disclosures Related to Reproductive Health Care (con.): The Presumption

- What if you did not provide the reproductive health care but you have information related to it?
- Enter the Presumption:
- “The reproductive health care provided by another person is **presumed lawful . . . unless**”:
 - (1) The covered entity/BA has **actual knowledge** it was not lawful or
 - (2) Requestor supplies factual information demonstrating a **substantial factual basis** that it was not lawful

Summary (so far)

- Purpose-based rule:
 - Cannot disclose PHI if the **purpose** is investigating/imposing liability for activities related to reproductive health care
 - If you reasonably determine the care was lawful or it is presumed to be lawful, the rule applies.
- But how do you know the purpose?

Attestation of the Purpose

- To be codified at 45 C.F.R. § 164.509
- Covered entities/business associates must get an attestation if:
 - The information is “potentially related to reproductive health care”
 - The information is requested for:
 - *Health oversight activities;*
 - *Judicial and administrative proceedings;*
 - *Law enforcement purposes; or*
 - *Disclosures to coroners or medical examiners.*

Attestations

- Must have all the required elements **and nothing else.**
- Cannot be combined with any other document.
- Must be in plain language.
- Attestations are not full safe harbors:
 - *Actual knowledge that material information is false.*
 - *Reasonable covered entity/business associate in the same position would not believe that the attestation regarding the purpose is true.*
 - *If covered entity/business associate later discovers information reasonably showing that any representation was materially false, leading to a prohibited use, they must cease disclosure.*
- HHS will put out model attestation forms.

Attestation Elements

- (1) Description of the information sought – identifying the individual/class whose information is sought;
- (2) Name of person/class being asked to disclosed;
- (3) Name of person/class disclosing to;
- (4) Statement that the purpose is not one of the prohibited purposes;
- (5) Statement that a person may be subject to criminal penalties under 42 U.S.C. § 1320d-6 for knowingly and in violation of HIPAA obtains information.
- (6) Signature of the person requesting the information (or authorized representative)

Limitations and Other Issues to Consider

- Does not protect PHI related to care that was illegal in the state it was provided in.
 - *This may be ambiguous in many circumstances.*
 - *The covered entity/business associate “reasonably determines.”*
- Protects patients, those providing care, and those facilitating care.
- Preempts state laws to the contrary (unless more stringent protections).

Other Changes

- Personal Representative change
- Permitted disclosures related to victims of abuse, neglect, or domestic violence change.
- Law enforcement permitted disclosure in response to administrative request/subpoena adds that the “response is required by law.”
 - *Not just reproductive health care.*

Other Changes to Definitions – 45 C.F.R. § 160.103

- Revised definition of “person” – meant as a clarification and to be consistent with 1 U.S.C. § 8.
 - Clarifies that the “natural person” part of the definition means “a human being who is born alive”
- Adds definition of “public health” – primarily to make clear that investigations and imposing liability for “the mere act of seeking, obtaining, providing, or facilitating health care” are not a public health activity

To Dos

- By December 23, 2024:
 - Update HIPAA policies and procedures.
 - Update training programs, especially for those who respond to requests for data.
 - Review BAAs and update if necessary.
- By February 16, 2026:
 - Updated NPP requirements (45 C.F.R. § 164.520).

Presenters



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Thank you!

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