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New Year, New Rules, No Excuses: Don't Miss the February 16, 2026 Part 2 and HIPAA Compliance Deadlines

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Jody Erdfarb, Wiggin and Dana LLP

On February 8, 2024, when the 42 C.F.R. Part 2 (Part 2) Final Rule was published, the February 16, 2026, compliance date seemed like a lifetime away. Now that the compliance date is rapidly approaching, it's time to take a second look at the Part 2 changes to ensure compliance.

These changes are the ultimate and long-awaited implementation by the U.S. Department of Health and Human Services (HHS) of the confidentiality provisions of Section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which was enacted on March 27, 2020, and required HHS "to align certain aspects of Part 2" with the Health Insurance Portability and Accountability Act (HIPAA) regulations.[1]

Remember that these changes affect not only Part 2 programs, which are "federally assisted" programs that hold themselves out as providing substance use disorder (SUD) services, but also their qualified service organizations, as well as any lawful holders of records generated from any Part 2 program, including potentially covered entities and business associates. Unlike HIPAA compliance, where compliance obligations are rooted on the classification of the individual or entity at issue, Part 2 compliance "follows the paper." This means that, once Part 2 records are generated by a Part 2 program, the Part 2 protections apply to whomever possesses the records. For example, a nursing home, which is not a Part 2 program, that is sent records from an opioid treatment program, which is a Part 2 program, must ensure that those records are treated in accordance with the Part 2 requirements (if the records are accompanied by a notice and a copy of the patient's consent).

The new regulations changed many of the Part 2 rules that were in place for decades. For an in-depth analysis of the revisions, listen to the October 29, 2025 webinar of the American Health Law Association's Behavioral Health and Health Information and Technology Practice Groups titled 42 C.F.R. Part 2: Recent Changes and New Risks for Substance Use Disorder Records (available on demand).

The following are some significant highlights:

Changes to Patient Consent Requirements

42 C.F.R. § 2.31 now allows Part 2 programs to employe a more user-friendly consent form. Instead of requiring "an explicit description of the SUD that may be disclosed," the consent may include only a description of the information to be used or disclosed that identifies the information "in a specific and meaningful fashion." Instead of requiring the name of the individuals or entities to which the disclosure is being made, the consent may designate a class of persons. In addition, the statement "at the request of the patient" is a sufficient description of the purpose when a patient initiates consent and does not provide a statement of the purpose.

Single TPO Consent Form

Perhaps most significantly, the revised Part 2 regulations permit the future use and disclosure of Part 2 records for treatment, payment, and health care operations (TPO) purposes based on a single consent signed by the patient. If the disclosure was for TPO purposes, HIPAA covered entities and business associates may then redisclose as permitted by the HIPAA rules, except for uses and disclosures for civil, criminal, administrative, and legislative proceedings against the individual. While this presents a major shift that allows providers to use streamlined forms that facilitate better care coordination without needing to update consent for every minor change in the care team, it also means that once a patient signs a single TPO consent, records disclosed to a HIPAA-covered entity lose some specific Part 2 protections as they move downstream. Moreover, HIPAA covered entities must still ensure that the Part 2 records are not used for certain law enforcement purposes. Part 2 programs that are not covered entities or business associates may redisclose only consistent with the consent. If the disclosure was for payment or health care operations, other lawful holders (that do not qualify as Part 2 programs or HIPAA covered entities or business associates) may redisclose as may be necessary for their contractors, subcontractors, or legal representatives to carry out the payment or health care operations specified in the consent on behalf of such lawful holders pursuant to a written contract.

For example, if a Part 2 program discloses Part 2 records to a patient's primary physician who is a HIPAA covered entity, based on the patient's consent for all future uses and disclosures for TPO, then that physician could subsequently redisclose the Part 2 records as permitted by HIPAA. If a Part 2 program discloses Part 2 records to a private outpatient SUD treatment center that is not a HIPAA covered entity based on a patient's consent for all future uses and disclosures for TPO, then that Part 2 program (the private outpatient SUD treatment center) could then redisclose the Part 2 records only for the purposes specified in the patient's consent. A new patient consent would be needed to use or disclose the records for a different purpose.

Note that the revised regulations prescribe specific content requirements for the single TPO consent form and stipulate that consent for use and disclosure of records (or testimony relaying information contained in a record) in a civil, criminal, administrative, or legislative investigation or proceeding cannot be combined with a consent to use and disclose a record for any other purpose. Each disclosure must include a copy of the consent or a clear explanation of the consent and a notice informing recipients that they may not use the records in proceedings absent specific patient consent or court order.

Request for Restrictions

Like in the HIPAA Privacy Rule, 42 C.F.R. § 2.26 now requires Part 2 programs to permit patients to request restrictions on TPO disclosures. Part 2 programs are only required to agree to the patient request if the disclosure is to a health plan for the purpose of carrying out payment or health care operations and is not otherwise required by law and is for services paid in full by the patient. Otherwise, Part 2 programs are not required to agree to any such patient request. However, if a Part 2 program agrees to the request, it may not use or disclose records in violation of such restriction, except in limited emergency situations. Interestingly, the *Federal Register* preamble language states that "covered entities should make every reasonable effort to the extent feasible to comply with a patient's request for a restriction,"[2] which is a seemingly higher standard than previously articulated by HHS.

Accounting of Disclosures

The new Part 2 regulations extended HIPAA's specific accounting of disclosure provisions to the Part 2 context. Pursuant to 42 C.F.R. § 2.25, a Part 2 program must provide a patient, upon request, an accounting of all disclosures made with consent in the three years prior to the date of the request, or a shorter time period chosen by the patient. The accounting of disclosures must meet HIPAA's requirements and is paused until HIPAA's accounting of disclosures provision at 45 C.F.R. §164.528 is revised to address accounting for TPO disclosures made through electronic health records.

Application of HIPAA Breach Notification Rules

42 C.F.R. § 2.16 simply states: "The provisions of 45 CFR part 160 and subpart D of 45 CFR part 164 shall apply to part 2 programs with respect to breaches of unsecured records in the same manner as those provisions apply to a covered entity with respect to breaches of unsecured protected health information." And, with that one sentence, the Part 2 regulations have been revised to create an entire new set of requirements for Part 2 programs to analyze, investigate, and report breaches, along with all of the associated costs. Covered entities are already familiar with these requirements, but Part 2 programs who have not had to report breaches before will need to quickly get up to speed to ensure compliance with these new requirements.

Enforcement

Part 2 noncompliance used to be primarily enforceable by criminal penalties, requiring a criminal level of intent. This imposed a high standard to penalize Part 2 programs. However, the revised regulations now implement the CARES Act requirement to apply civil penalties to a Part 2 program for a violation of the confidentiality provisions in the same way that they are applied to a covered entity or business associate for a HIPAA violation. Part 2 civil enforcement will follow HIPAA's tiered civil monetary penalty structure, based on the level of intent attributed to the violator (from an unknowing violation that could not have been known with reasonable diligence, to willful neglect that is not corrected within 30 days). The highest penalty amounts (before accounting for the 2026 inflationary increase) may reach up to $2,134,831 for all violations of an identical requirement per calendar year.[3]

On August 27, 2025, HHS Secretary Robert Kennedy Jr. delegated authority to the HHS Office for Civil Rights (OCR) to enforce Part 2.[4] OCR is authorized to impose civil money penalties; enter into resolution agreements, monetary settlements, and corrective action plans to resolve indications of noncompliance; and issue subpoenas requiring the attendance and testimony of witnesses and the production of any evidence that relates to any matter under investigation or compliance review for failure to comply. If OCR takes the same approach to Part 2 enforcement as it does with HIPAA enforcement, this will be a drastic change since Part 2 enforcement actions have been virtually nonexistent in the past.

Civil, Criminal, Administrative, or Legislative Proceedings

Part 2 always prohibited the use of Part 2 information in criminal and civil proceedings, but the revised regulations now added administrative and legislative proceedings. This shield is comprehensive: it prohibits the use of records or verbal testimony in applications for warrants or as evidence in any federal, state, or local authority proceeding against a patient. Crucially, these legal protections cannot be waived through general consent. Under the new rules, patient consent for disclosure in a legal proceeding must be a standalone document; it cannot be combined with consent for TPO or any other purpose. Absent this specific, unbundled consent, a Part 2-compliant court order is required to use or disclose records in any such proceeding.

Notice of Privacy Practices

In 42 C.F.R. § 2.22, the new regulations revise the content requirements for the notice that Part 2 programs are required to provide patients upon admission to better align with HIPAA and to incorporate the new patient rights provided to Part 2 patients.

Separately, pursuant to OCR's April 26, 2024 Final Rule, "HIPAA Privacy Rule To Support Reproductive Health Care Privacy,"[5] HIPAA covered entities and business associates must also revise their Notices of Privacy Practices (NPPs) by February 16, 2026 to conform to the Part 2 regulatory changes. While much of the HIPAA Final Rule was vacated by a Texas federal court, the requirement for covered entities to revise their NPPs is still in effect. The NPPs must be revised as follows:

- Covered entities that create or maintain Part 2 records must include in their NPP a description of the ways in which they may use and disclose Part 2 records, and of the individual's rights and the

covered entities' responsibilities with respect to such records.

- Where the NPP describes uses or disclosures that are permitted for TPO or without an authorization, the description must reflect "other applicable law" that is more stringent than the Privacy Rule, including Part 2.
- Likewise, where the NPP describes uses and disclosures that are permitted for TPO or without an authorization sufficiently to place an individual on notice of the uses and disclosures that are permitted or required by the Privacy Rule and other applicable law, Part 2 must be included.
- A statement explaining that SUD treatment records received from programs subject to Part 2, or testimony relaying the content of such records, may not be used or disclosed in civil, criminal, administrative, or legislative proceedings against the individual unless based on written consent, or a court order after notice and an opportunity to be heard must be provided to the individual or the holder of the record. A court order authorizing use or disclosure must be accompanied by a subpoena or other legal requirement compelling disclosure before the requested record is used or disclosed.
- A statement explaining that, if a covered entity that creates or maintains records subject to Part 2 intends to use or disclose such records for fundraising for the benefit of the covered entity, the individual must first be provided with a clear and conspicuous opportunity to elect not to receive any fundraising communications.

While many health care providers have been waiting for OCR and/or the Substance Abuse and Mental Health Services Administration to issue model notices that comply with the regulatory changes, there has been no official indication that any such models will be released prior to the compliance date. Therefore, Part 2 programs and HIPAA covered entities should be actively revising their notices now to ensure compliance. Note that a health care provider that is both a Part 2 program and a HIPAA covered entity may integrate the notices into one NPP that complies with both sets of laws.

The time for procrastination has come to an end. Health care providers must examine their policies, procedures, and forms to ensure compliance with these new requirements. With the risk of increased Part 2 enforcement looming, now is the time to act.

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[1] HHS, *Fact Sheet 42 CFR Part 2 Final Rule*, https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html.

[2] 89 Fed. Reg. 12472, 12540 (Feb. 16, 2024), https://www.govinfo.gov/content/pkg/FR-2024-02-16/pdf/2024-02544.pdf.

[3] 89 Fed. Reg. 64815 (Aug. 8, 2024), https://www.govinfo.gov/content/pkg/FR-2024-08-08/pdf/2024-17466.pdf.

[4] 90 Fed. Reg. 41833, 41834 (Aug. 27, 2025), https://www.govinfo.gov/content/pkg/FR-2025-08-27/pdf/2025-16391.pdf.

[5] 89 Fed. Reg. 32976, 33045-22048 (Apr. 26, 2024), https://www.govinfo.gov/content/pkg/FR-2024-04-26/pdf/2024-08503.pdf.

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Health Information and Technology Practice Group Behavioral Health Health Information

1099 14th Street NW, Suite 925, Washington, DC 20005 | P. 202-833-1100

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