Coppersmith Briefs

The Eagle Has Landed:
How the CARES Act Final Rule is Changing 42 CFR Part 2 Compliance for Health Care Providers, Health Plans and Health Information Networks/Exchanges

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INTRODUCTION

On February 16, 2024, the Department of Health and Human Services (HHS), through the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office for Civil Rights (OCR), published the final rule modifying 42 CFR Part 2 to implement Section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (the "CARES Act Final Rule"). The CARES Act Final Rule is effective April 16, 2024. **The compliance deadline is February 16, 2026**. Early voluntary compliance any time after the April 16 effective date is permitted.[1]

This Coppersmith Brief summarizes the most significant Part 2 rule changes and puts those changes into context for health care providers, health plans and health information networks/exchanges (HIN/HIEs). If you have questions or concerns about how the changes to the Part 2 regulations might affect your organization, please contact us at msoliz@cblawyers.com.

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THE SUD DATA PRIVACY LANDSCAPE

A Brief History of 42 CFR Part 2

Since the 1970s, individuals receiving substance use disorder (SUD) treatment services from certain SUD treatment providers have been protected by a stringent federal privacy law found at 42 USC 290dd-2 and 42 CFR Part 2 (the "Part 2 regulations") (collectively, "Part 2"). The statute requires that:

> Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance use disorder education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) [Part 2 nonapplicability], be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) [permitted disclosures].[2]

The Part 2 regulations implement this statutory requirement by prohibiting federally funded SUD treatment programs (called "Part 2 programs") from disclosing patient identifying information that would identify a patient as having (or having had) a SUD (collectively, "Part 2 records") without a special type of written consent or court order, unless one of the few Part 2 exceptions to the consent requirement applied.[3] The intent behind this law was (and is) to encourage individuals suffering from SUDs to seek treatment without the fear of stigma and retaliation by making their Part 2 record top secret. Unfortunately, this approach has also effectively rendered SUD patients invisible to the health care system and deprived SUD patients from the benefits of integrated care.

Unlike HIPAA,[4] Part 2 generally did not permit a patient's care team and third-party payers (including health plans) to share a patient's Part 2 record with each other for non-emergency treatment, payment and health care operations (TPO) purposes, without the patient's written consent that named the specific recipient of the Part 2 records. Consequently, SUD patients have often been left behind in the move toward integrated and whole-person care, as their electronic Part 2 records cannot be easily shared with their care teams for TPO purposes, because standardized data segmentation, consent management, and the supporting technical and administrative infrastructure simply do not exist.

Attempts were made by SAMSHA in 2017, 2018 and 2020 to modernize the Part 2 regulations to accommodate the shift to whole person care and interoperable health IT. However, the agency was limited in what it could accomplish within its regulatory authority without a change to 42 USC 290dd-2. Congress sought to change that with the passage of the CARES Act.

Section 3221 of the CARES Act

On March 27, 2020, Congress passed the CARES Act to provide emergency assistance to individuals, families, and businesses affected by the COVID-19 pandemic.[5] Section 3221 of the CARES Act—Confidentiality and Disclosure of Records Relating to Substance Use Disorder—amended 42 USC 290dd-2 to align the Part 2 privacy standards more closely with HIPAA's privacy standards, breach notification requirements, and enforcement authority. Congress further directed HHS to revise the Part 2 regulations to implement these statutory amendments. Until that time, HHS directed that the then-current Part 2 regulations remain in effect notwithstanding the statutory change.

If you are interested in reading more about the CARES Act changes to 42 USC 290dd-2, please read our Coppersmith Brief, The CARES Act: Sweeping Changes to Substance Use Disorder Privacy Law (42 USC 290dd-2).

The CARES Act Proposed Rule

More than two years after the passage of the CARES Act, on November 28, 2022, HHS through SAMSHA and OCR issued a Notice of Proposed Rulemaking (NPRM) to revise the Part 2 regulations (the "CARES Act Proposed Rule") to implement Section 3221 of the CARES Act.[6]

HHS proposed to do all of the following in the NPRM:

- Align Part 2 definitions with HIPAA;
- Shift Part 2 enforcement to HHS and apply HIPAA civil and criminal penalties to Part 2 programs;
- Apply HIPAA breach notification standards to breaches of Part 2 records by Part 2 programs;
- Limit the applicability of Part 2 by excluding health plans from the definition of a third-party payer;
- Expand the applicability of Part 2 by aligning Part 2's de-identification standard with HIPAA's definition, thereby making HIPAA limited data sets (LDS) containing information from Part 2 records subject to Part 2;
- Modify the required Part 2 confidentiality notice requirement applicable to Part 2 programs to align with the HIPAA Notice of Privacy Practices (NPP);
- Modify the HIPAA NPP for covered entities that receive or maintain Part 2 records to include a provision limiting redisclosure of Part 2 records for legal proceedings according to Part 2 requirements, among other changes;
- Permit Part 2 programs to use and disclose Part 2 records based on a single prior consent signed by the patient for all future uses and disclosures for TPO purposes;
- Permit the redisclosure of Part 2 records for any HIPAA-permitted purposes by recipients that are Part 2 programs or HIPAA regulated entities (*i.e.*, covered entities or business associates),[7] with certain exceptions;
- Retain the requirement to transmit a prohibition on redisclosure with each disclosure of Part 2 records made pursuant to a patient's consent;
- Retain certain redisclosures limitations and notice/accounting requirements on the disclosure of Part 2 records through intermediary organizations, like HIN/HIEs and electronic health record (EHR) system;
- Expand prohibitions on the use and disclosure of Part 2 records in civil, criminal, administrative, or legislative proceedings conducted by a federal, state, or local authority against a patient, without a Part 2-compliant court order or the patient's Part 2-compliant consent;
- Align patient rights under Part 2 with individual rights under HIPAA, including the right to request restrictions on the disclosure of Part 2 records for TPO purposes and a right to an accounting of disclosures;
- Require disclosures to the HHS Secretary for enforcement of Part 2;
- Require Part 2 programs to: (1) establish a process for receiving Part 2 complaints; (2) prohibit retaliation for filing a complaint; and (3) prohibit waiver of the right to file a complaint as a condition of providing treatment, enrollment, payment, or eligibility for services; and
- Permit investigative agencies to apply for a court order to use or disclose Part 2 records after they unknowingly receive Part 2 records in the course of investigating or prosecuting a Part 2 program, when certain preconditions are met.

HHS also sought comment on:

- Whether to create a subset of Part 2 records—SUD counseling notes—that would be similar to a HIPAA psychotherapy note and subject to additional privacy protections; and
- Whether it should impose a consent or opt out requirement for the use of Part 2 records to create de-identified data sets or to use Part 2 records for fundraising.

For a more thorough summary of the CARES Act Proposed Rule, please see our Coppersmith Brief, Has the Eagle Landed?: HHS' Proposed Changes to 42 CFR Part 2 to Align Substance Use Disorder Privacy Protections with HIPAA.

A year and half later, on February 8, 2024, HHS announced the release of the CARES Act Final Rule. Many of The CARES Act Proposed Rule changes were finalized in the CARES Act Final Rule, but not all. A summary comparison chart of the material differences between the CARES Act Proposed Rule and the CARES Act Final Rule is included in Appendix A. The section below summarizes the significant Final Rule changes to the Part 2 regulations.

SUMMARY OF THE CARES ACT FINAL RULE CHANGES

The CARES Act Final Rule was published in the Federal Register on February 26, 2024. It is effective April 16, 2024, but the compliance deadline is delayed until February 16, 2026—giving Part 2 programs and other lawful holders of Part 2 records up to two years to get ready for compliance. Voluntary compliance after the effective date (April 16, 2024) is permitted.

Enforcement Structure

One of the most significant changes brought about by the CARES Act and the CARES Act Final Rule is the enforcement structure shift away from only title 18 criminal prosecutions brought by the Department of Justice (DOJ) to HHS under a robust complaint, breach reporting, and enforcement/penalty structure that leverages HIPAA's civil/criminal penalties and the HIPAA Enforcement Rule (see 164 CFR Part 160, Subparts C, D, and E). This change significantly raises the risks associated with Part 2 noncompliance for the following reasons:

- There has been little visibility into Part 2 violations because of the historically decentralized complaint structure and lack of any regulatory reporting requirement. The changes to Part 2 centralize complaints, reporting and enforcement with HHS (although the exact enforcement agency within HHS is yet to be determined).

- Historically, DOJ has not actively exercised its criminal enforcement authority against Part 2 programs or other lawful holders of Part 2 records for noncompliance with Part 2. HHS, on the other hand, actively conducts compliance reviews and investigations through OCR, and exercises its civil enforcement authority.

- Adoption of the HIPAA enforcement/penalty structure will give state attorneys general the right to enforce Part 2 through civil suits on behalf of state residents.

We more thoroughly explain the CARES Act Final Rule's changes to the entire Part 2 enforcement structure below.

Complaints (42 CFR 2.4)

The CARES Act Final Rule rewrites Section 2.4 (Reports of Violations) of the Part 2 regulations. It replaces the process for filing complaints with the U.S. Attorney for the judicial district in which the Part 2 violation occurred (or SAMHSA if the violation concerned an opioid treatment program) with an internal and external complaint process.

The CARES Act Final Rule requires Part 2 programs (but not other lawful holders) to:

- Provide an internal process for receiving Part 2 complaints;
- Not retaliate (*e.g.*, intimidate, threaten, coerce, or discriminate) against any patient for complaining or exercising any other right under Part 2; and
- Not require patients to waive their right to file a complaint as a condition of treatment, payment, enrollment, or eligibility.

Additionally, the CARES Act Final Rule provides that a person—*i.e.*, a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private—may file a complaint with HHS

for any Part 2 violation by a Part 2 program, covered entity, business associate, qualified service organization (QSO), or lawful holder in the same manner as a person may file a complaint under HIPAA (see 45 CFR 160.306).

Enforcement & Penalties (42 CFR 2.3)

Under the CARES Act Final Rule changes:

- Any person—*i.e.*, a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private—who violates 42 USC 290dd-2(a)-(d) will be subject to penalties under 42 USC 1320d-5 (civil penalties) and d-6 (criminal penalties); and
- The HIPAA Enforcement Rule (45 CFR Part 160, Subparts C, D and E) applies to any noncompliance with Part 2. Subpart C covers compliance and investigations; Subpart D addresses the imposition of monetary penalties; and Subpart E establishes the procedures for hearings.

Thus, persons subject to the Part 2 regulations may face the following consequences for violations of, or noncompliance with, Part 2:

- HHS compliance audits and investigations;
- Technical assistance;
- Corrective action plans and resolution agreements;
- HHS civil monetary penalties;
- DOJ criminal enforcement of criminal penalties for knowing or intentional violations; and
- Civil suits brought by state attorneys general on behalf of state residents.[8]

(Please note that neither the CARES Act nor the CARES Act Final Rule provides patients with a private right of action for Part 2 violations.[9])

HHS plans to "identify the enforcing agency [within HHS] before the compliance date of this final rule."[10] It is unclear whether persons who opt for voluntary compliance with the rule changes will also be subject to early enforcement actions. However, HHS has implied in the commentary to the CARES Act Final Rule that it will not implement this enforcement structure before the compliance date (February 16, 2026).

Additionally, Part 2 programs and other lawful holders of Part 2 records should take note that the strict construction language in Section 2.2 (Purpose and Effect)—which required that the Part 2 regulations be "construed strictly in favor of the potential violator"—has been removed.

Safe Harbor Protection for Investigative Agencies (42 CFR 2.3(b) and 2.66)

Other lawful holders of Part 2 records should also take note that HHS declined requests to extend safe harbor protection from criminal and civil liability to health care providers, health plans, HIN/HIE and others (other than investigative agencies) that inadvertently violate Part 2 because they were unaware that they were maintaining Part 2 records.[11] An "investigative agency" is defined as "a Federal, state, Tribal, territorial, or local administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the activities of a part 2 program or other person holding records under this part."[12]

Under the CARES Act Final Rule, the only other lawful holders of Part 2 records that have safe harbor protection are investigative agencies when, in the course of investigating or prosecuting a Part 2 program or other lawful holder of Part 2 records, they unknowingly receive Part 2 records without first obtaining a Part 2-compliant court order. This safe harbor protection is not available in investigations against the patient. Moreover, to qualify for it, the persons acting on behalf of an investigative agency must act "with reasonable diligence" to determine in advance whether Part 2 applied to the records. Under the CARES Act Final Rule, reasonable diligence means taking all of the following actions where it is reasonable to believe that the practice or provider provides SUD diagnostic, treatment, or referral for treatment services:

(i) Searching for the practice or provider among the substance use disorder treatment facilities in the online treatment locator maintained by SAMHSA;
(ii) Searching in a similar state database of treatment facilities where available;
(iii) Checking a provider's publicly available website, where available, or its physical location to determine whether in fact such services are provided;
(iv) Viewing the provider's Patient Notice or the HIPAA NPP if it is available online or at the physical location; and
(v) Taking all these actions within a reasonable period of time (no more than 60 days) before requesting records from, or placing an undercover agent or informant in, a health care practice or provider.[13]

Investigative agencies must also report annually the following information:

- The number of applications for a court order authorizing the use and disclosure of the records and any records later obtained or the placement of an undercover agent or information in a Part 2 program as an employee or patient during the calendar year;
- The number of instances in which such applications were denied, due to findings by the court of Part 2 violations during the calendar year; and
- The number of instances in which Part 2 records were returned or destroyed following unknowing receipt without a court order during the calendar year.[14]

Additionally, HHS made changes to Section 2.66 to create a process for what investigative agencies must do once if they discover they received Part 2 records in the course of investigating or prosecuting a Part 2 program without a Part 2-compliant court order.

Breach Reporting (42 CFR 2.11 and 2.16(d))

The requirements of the HIPAA Breach Notification Rule are now applicable to Part 2 programs. Specifically, HHS finalized changes to the Part 2 regulations to require that the Breach Notification Rule "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." HHS also finalized the HIPAA definition of "breach" in Section 2.11. However, in the commentary to the CARES Act Final Rule, HHS explains that Part 2 programs are required to report not only HIPAA breaches, but the unauthorized use or disclosure of Part 2 records in violation of Part 2. HHS explains:

> Section 290dd-2(k), as added by the CARES Act, required the Department to adopt the term "breach" in part 2 by reference to the definition in 45 CFR 164.402 of the HIPAA Breach Notification Rule. HIPAA defines "breach" as "the acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E which compromises the security or privacy of the protected health information." HIPAA also describes the circumstances that are considered a "breach" and explains that a breach is presumed to have occurred when an "acquisition, access, use, or disclosure" of PHI occurs in a manner not permitted under the HIPAA Privacy Rule unless a risk assessment shows a low probability that health information has been compromised.
>
> To implement section 290dd-2(j) added by section 3221(h) of the CARES Act, which requires notification in case of a breach of part 2 records, we reference and incorporate the HIPAA breach notification provisions. . . .

> We believe the discussion above makes clear that the definition should be applied to records under part 2 instead of PHI under HIPAA, and **we further clarify that breach includes use and disclosure of part 2 records in a manner that is not permitted by part 2**.[15]

Notably, this expanded breach reporting requirement does not apply to other lawful holders of Part 2 records (including QSOs) that are not Part 2 programs.

Part 2 Applicability and Part 2 Records

Neither the CARES Act nor the CARES Act Proposed Rule or CARES Act Final Rule make changes to the applicability of Part 2 to Part 2 programs. However, the CARES Act Final Rule does change the scope of applicability of Part 2's use and disclosure restrictions to health plans; clarifies the applicability of Part 2 provisions to other lawful holders of Part 2 records as well as who qualifies as a QSO; adopts the HIPAA de-identification standard; and creates a new subset of Part 2 records, called SUD counseling notes.

Health Plans (42 CFR 2.11)

The CARES Act Final Rule finalized the proposal in the CARES Act Proposed Rule to exclude "health plans" (as defined by HIPAA)[16] from the definition of "third-party payer." A "third-party payer" under the revised regulations is thus defined as:

> A person, other than a health plan as defined at 45 CFR 160.103, who pays or agrees to pay for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of the patient's family or on the basis of the patient's eligibility for Federal, state, or local governmental benefits.[17]

In the commentary to the CARES Act Final Rule, HHS further explains that business associates of health plans are not "third-party payers" under the new definitions.[18]

This change is significant because it narrows the scope of when Part 2's use and disclosure restrictions apply to health plans and their third party administrators (TPAs). Under this regulatory change, the Part 2 applicability prong in Section 2.12(d)(2)(A)—which extends Part 2's restrictions on the use and disclosure of Part 2 records to third-party payers that receive Part 2 records from Part 2 programs—no longer applies to health plans. Health plans that do not operate Part 2 programs are therefore only subject to Part 2's disclosure restrictions if they receive Part 2 records with the required notice of the prohibition on redisclosure or otherwise meet the definition of a lawful holder (*i.e.*, they receive the Part 2 records pursuant to an exception, please see the Section on Lawful Holders).

HHS also took care to ensure that the exclusion of health plans from the third-party payer definition did not preclude use of certain Part 2 exceptions that allow for the disclosure of Part 2 records to third-party payers without patient consent. For example, HHS made changes to Section 2.15 (Patients who lack capacity and deceased patients) and Section 2.53 (Management audits, financial audits, and program evaluation) to include health plans—in addition to third-party payers—as permitted recipients of Part 2 records.

Lawful Holders (42 CFR 2.11)

The CARES Act Final Rule also adds a definition of "lawful holder" that includes a wider scope of persons than those who are explicitly subject to Part 2's use and disclosure restrictions in 42 CFR 2.12(d)(2). Section 2.12(d)(2) limits Part 2's use and redisclosures restrictions to the following persons:

- Third-party payers (excluding health plans) with regard to Part 2 records disclosed to them by Part 2 programs;
- Persons who have direct administrative control over Part 2 programs with regard to the Part 2 records; and

- Persons who receive records directly from a Part 2 program, a HIPAA regulated entity or other lawful holder and who are notified of the prohibition on redisclosure. Moreover, such recipients who are health care providers who are not Part 2 programs can document information about the SUD in their own records and that documentation is not subject to the restrictions of Part 2.

By contrast, "[l]awful holder" is broadly defined as "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. (2) One of the exceptions to the written consent requirements in 42 U.S.C. 290dd-2 or this part."[19] HHS declined commentators' requests to exclude HIPAA regulated entities from the definition of "lawful holder."[20]

The broad definition of "lawful holder" is notable because lawful holders are subject to a number of Part 2 requirements, including, for example:

- The new complaint and enforcement provisions;
- The prohibition on using or disclosing Part 2 records to initiate or substantiate criminal charges against a patient or to conduct any criminal investigation of a patient, or to use in any civil, criminal, administrative, or legislative proceedings against a patient;
- The requirement to limit redisclosures of Part 2 records to only that information which is necessary to carry out the purpose of the disclosure;
- The requirement to have Part 2 policies and procedures in place to protect against the unauthorized use and disclosure of patient identifying information (except for lawful holders who are family members, friends or other informal caregivers);
- The requirement to provide the prohibition on redisclosure notice and copy of the consent/consent explanation for consent-based disclosures;
- The prohibition on reporting to prescription drug monitoring programs without patient consent;
- If applicable, the requirements for complying with the audit and evaluation provisions, as well as relevant research provisions if the lawful holder is a HIPAA regulated entity; and
- The requirement to have certain contracts in place with downstream contractors if the lawful holder is holding the Part 2 records as a consent recipient and the lawful holder is not a HIPAA regulated entity.

Because the applicability provision in 42 CFR 2.12(d) differs from the scope of a "lawful holder," it is now unclear whether the FDA or medical personnel who receive Part 2 records under the medical emergency exception, but who do not receive the prohibition on redisclosure notice because it is not a consent-based disclosure, are subject to Part 2's use and disclosure restrictions. Moreover, persons who do not receive the Part 2 records pursuant to an exception, or pursuant to a consent without receiving the prohibition on redisclosure, presumably are not subject to Part 2 because they don't satisfy the definition of a "lawful holder" or the conditions of applicability in 42 CFR 2.12(d). However, HHS' statements in the CARES Act Final Rule regarding the applicability of HIPAA's penalty tiers for unknowing violations of Part 2 suggests that HHS may seek to enforce Part 2 against such persons.[21]

Qualified Service Organizations (42 CFR 2.11 and 2.12(c)(4))

In the CARES Act Final Rule, HHS added clarifying language that a Qualified Service Organization (QSO) includes a person who is a HIPAA business associate and receives Part 2 records that also qualify as protected health information (PHI). HHS felt it was necessary to make this change to clarify that a QSO includes a person who performs work "on behalf of" a Part 2 program.[22]

Unfortunately, HHS declined to modify the definition of QSOs to include subcontractors of QSOs or to allow QSO-to-QSO disclosures without consent or application of another Part 2 exception. QSOs must continue to operate under 2010 guidance that limits QSO redisclosures to subcontractors without consent to only those subcontractors who qualify as

"contract agents." HHS declined to provide further guidance on what constitutes a "contract agent," instead pointing to statements made in the 2020 rule changes that suggest this concept overlaps with "those articulated in § 2.33(b) related to information disclosures to a lawful holder's contractors, subcontractors, and legal representatives for the purposes of payment and/or health care operations."[23]

HHS further declined to apply the new breach reporting requirements for Part 2 programs to QSOs because the CARES Act only authorized expansion of the breach reporting requirements to Part 2 programs.[24] However, HHS expects that Part 2 programs will address breach notification requirements in Qualified Service Organization Agreements (QSOA) with QSOs.

The Part 2 De-Identification Standard (42 CFR 2.11, 2.16, 2.52, and 2.54)

Prior to the CARES Act Final Rule changes, Part 2's standard for "patient identifying information" and the corresponding de-identification standard were different from HIPAA's standards for "individually identifiable health information" and "de-identification."[25] For example, Part 2 historically excluded medical record numbers from the definition of "patient identifying information"[26] and allowed Part 2 programs and other lawful holders to adopt de-identification policies that only removed direct HIPAA identifiers, but allowed for the inclusion of indirect identifiers (*i.e.*, dates related to patients, geographic subdivisions above street address, and numbers or codes assigned to patients).[27] Consequently, it's been common in the industry for HIPAA regulated entities, in particular, to include information from Part 2 program records in HIPAA limited data sets (LDS) (*e.g.*, data sets stripped of direct, but not indirect, identifiers) subject to a HIPAA data use agreement (DUA) that prohibits re-identification of individuals.[28] However, such data sets will need to be reassessed for Part 2 compliance under the revised Part 2 regulations because they'll be subject to Part 2 under the new Part 2 de-identification standard.

In the CARES Act Final Rule, HHS decided to adopt HIPAA's standard for de-identification (see 45 CFR 164.514(b)), which requires that data sets including information from Part 2 records be stripped of ***all*** HIPAA direct and indirect identifiers or be subject to an expert determination that the data set is de-identified, in order to not be subject to Part 2.[29] HHS further declined to adopt the HIPAA concept of a LDS subject to a DUA into the Part 2 regulations.[30] Accordingly, stripping Part 2 records of direct identifiers and requiring that recipients sign a HIPAA DUA is no longer sufficient to render the data set de-identified for Part 2 purposes.

In the CARES Act Proposed Rule, HHS also considered imposing an opt-in (consent) requirement for de-identifying Part 2 records. Fortunately, HHS declined to impose such a requirement in the CARES Act Final Rule on the ground that it would be inconsistent with and potentially hinder the CARES Act requirement that the Part 2 regulations expressly permit the disclosure of de-identified Part 2 records for public health purposes (see the Section on the Public Health Exception).[31]

Subset of Part 2 Records: SUD Counseling Notes (42 CFR 2.11)

The CARES Act Final Rule creates a new definition for a SUD clinician's notes that is analogous to HIPAA's definition of "psychotherapy notes."[32] 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."[33] 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.[34] Thus, like HIPAA psychotherapy notes, the key feature of Part 2's SUD counseling notes are that they are maintained separately from the rest of a patient's medical record.

The Part 2 Notice and HIPAA NPP (42 CFR 2.22)

Since its inception, Part 2 has required Part 2 programs to give patients notice of Part 2's confidentiality requirement upon their admission to the Part 2 program. This is sometimes referred to as a "Part 2 summary" or "Part 2 notice." In the CARES Act Final Rule, HHS finalized requirements to align the Part 2 notice requirements with HIPAA as well as changes to Part 2's enforcement structures. The changes are tantamount to a complete rewrite of the Part 2 notice requirements. Consequently, Part 2 programs will need to rewrite their Part 2 notices on or before the February 16, 2026 compliance deadline.

For HIPAA regulated entities, the Part 2 notice may be combined with the HIPAA NPP. HHS also initially proposed to make changes to the HIPAA NPP requirements as part of the Part 2 rule changes. However, in the CARES Act Final Rule, HHS declined to finalize those rule changes, explaining that:

> The Department intends to publish the CARES Act required revisions to the HIPAA NPP provision (45 CFR 164.520) as part of a future HIPAA rulemaking. Thus, this final rule focuses only on changes to the Patient Notice under § 2.22. We intend to align compliance dates for any required changes to the HIPAA NPP and Part 2 Patient Notice to enable covered entities to makes such changes at the same time.[35]

Patient Consent and Downstream Uses and Redisclosures of Part 2 Records

A TPO Consent (42 CFR 2.33(a))

Neither the CARES Act nor the CARES Act Final Rule changes the fundamental requirement in 42 CFR 2.33 that, unless an exception applies, a valid Part 2-compliant consent is required to use and disclose Part 2 records, including for TPO purposes. Nor do they alter the right to revoke consent at any time and for any reason.

Per Section 3221 of the CARES Act, HHS has finalized in Section 2.33(a) of the Part 2 regulations that:

- A patient may execute a single part Part 2-compliant consent that covers all future uses and disclosures of Part 2 records for TPO purposes, unless revoked; and
- When such a TPO consent is executed, a Part 2 program or HIPAA regulated entity may use and disclose those Part 2 records as permitted by HIPAA for TPO purposes, unless revoked.

In doing so, HHS has also finalized changes to align the Part 2 consent requirements with HIPAA authorization elements (see Required Part 2 Consent Elements) and created new consent-based ***redisclosure*** permissions for ***recipients*** of Part 2 records depending on the type of consent and the type of recipient (see New Consent-Based Disclosure Rules). Importantly, the much talked about broader permissions for Part 2 programs and HIPAA regulated entities to use and disclose Part 2 records for any purpose permitted by HIPAA (excluding use or disclosure in proceedings against the patient) apply only to ***redisclosures*** of the Part 2 records by a ***HIPAA regulated entity recipient*** of the Part 2 records pursuant to a TPO consent.[36]

Required Part 2 Consent Elements (42 CFR 2.31)

HHS has finalized the Part 2 consent elements to partially (but not fully) align with HIPAA authorization elements. A Part 2 consent continues to remain materially different from a HIPAA authorization and may be combined with a HIPAA authorization to form a combined Part 2 consent/HIPAA authorization. Importantly, in the CARES Act Final Rule, HHS revised the definition of "intermediary" to exclude HIPAA regulated entities. As a result, the consent requirements applicable to intermediaries and redisclosures through intermediaries do not apply if the intermediary is a HIPAA regulated entity.[37]

Current (42 CFR 2.31)	Final (42 CFR 2.31)	Summary of Change
(1) The name of the patient.	(1) The name of the patient.	No change.
(2) The specific name(s) or general designation(s) of the Part 2 program(s), entity(ies), or individual(s) permitted to make the disclosure.	(2) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.	Technical alignment with HIPAA. No material change.
(3) How much and what kind of information is to be disclosed, including an explicit description of the substance use disorder information that may be disclosed.	(3) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.	Substantive change and alignment with HIPAA. The requirement to include an "explicit description" of the information has been replaced with the HIPAA requirement to describe the information in a "specific and meaningful fashion." In the commentary to the CARES Act Final Rule, HHS explains that the consent must specifically authorize the disclosure of the Part 2 record.[38]
(4)(i) *General requirement for designating recipients.* The name(s) of the individual(s) or the name(s) of the entity(-ies) to which a disclosure is to be made.	(4)(i) *General requirement for designating recipients.* The name(s) of the person(s), or class of persons, to which a disclosure is to be made ("recipient(s)"). For a single consent for all future uses and disclosures for treatment, payment, and health care operations, the recipient may be described as "my treating providers, health plans, third-party payers, and people helping to operate this program" or a similar statement.	Substantive change and partial alignment with HIPAA. The requirement to specifically name the recipient has been replaced with the HIPAA permission to name the class of recipients. It is unclear whether HHS intends the illustrative list of generally designated recipients for a TPO consent to limit the classes of persons eligible for the general designation.
(4)(ii) *Special instructions for entities that facilitate the exchange of health information and research institutions.* Notwithstanding paragraph (a)(4)(i) of this section, if the recipient entity facilitates the exchange of health information or is a research institution, a written consent must include the name(s) of the entity(-ies) and (A) The name(s) of individual or entity participant(s); or (B) A general designation of an individual or entity participant(s) or class of participants that must be	(4)(ii) *Special instructions for intermediaries*. Notwithstanding paragraph (a)(4)(i) of this section, if the recipient entity is an intermediary, a written consent must include the name(s) of the intermediary(ies) and (A) The name(s) of the member participants of the intermediary; or (B) A general designation of a participant(s) or class of participants, which must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being	Technical changes and a substantive change to remove the requirement that the consent form contain a statement regarding the patient's right to a list of disclosures made by the intermediary. However, intermediaries are still required to provide such accountings to patients, upon request (see the Section on Accounting Requirements for Part 2 Programs and Intermediaries). HHS further modified the definition of "intermediary" in the CARES Act Final Rule to exclude HIPAA regulated

Current (42 CFR 2.31)	Final (42 CFR 2.31)	Summary of Change
limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed. When using a general designation, a statement must be included on the consent form that the patient (or other individual authorized to sign in lieu of the patient), confirms their understanding that, upon their request and consistent with this part, they must be provided a list of entities to which their information has been disclosed pursuant to the general designation (see § 2.13(d)).	used or disclosed.	entities. Accordingly, the restrictions on disclosures and redisclosures through an intermediary organization are limited to those instances where the intermediary is not a HIPAA regulated entity.
N/A	(4)(iii) *Special instructions when designating certain recipients.* 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.	Substantive change. Additional content must be added to a TPO consent to provide the patient with notice of the downstream uses and redisclosures of the Part 2 record when the recipient is a HIPAA regulated entity.
(5) The purpose of the disclosure. In accordance with § 2.13(a), the disclosure must be limited to that information which is necessary to carry out the stated purpose.	(5) A description of each purpose of the requested use or disclosure. (i) The statement "at the request of the patient" is a sufficient description of the purpose when a patient initiates the consent and does not, or elects not to, provide a statement of the purpose. (ii) The statement, "for treatment, payment, and health care operations" is a sufficient description of the purpose when a patient provides consent once for all such	Substantive changes to align with HIPAA, to support use of a TPO consent and, if applicable, notice of the patient's right to opt out of any fundraising communications. In the CARES Act Final Rule, HHS declined to require a separate opt-in consent for fundraising activities.[39] Although not required, HHS suggests including a statement in TPO consents that "patient consent is needed (or required) to allow the program to use

Current (42 CFR 2.31)	Final (42 CFR 2.31)	Summary of Change
	future uses or disclosures for those purposes. (iii) *Fundraising.* If a Part 2 program intends to use or disclose records to fundraise on its own behalf, a statement about the patient's right to elect not to receive any fundraising communications.	and disclose the patient's records for TPO (or 'to help the program operate its health care business') or something similar."[40] HHS also notes in the commentary to the CARES Act Final Rule that the existing restriction in Section 2.13 (Confidentiality restrictions and safeguards) will continue to require that "[a]ny use or disclosure made under the regulations in this part must be limited to that information which is necessary to carry out the purpose of the use or disclosure."[41]
(6) A statement that the consent is subject to revocation at any time except to the extent that the Part 2 program or other lawful holder of patient identifying information that is permitted to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third-party payer.	(6) The patient's right to revoke the consent in writing, except to the extent that the Part 2 program, or other lawful holder of patient identifying information that is permitted to make the disclosure, has already acted in reliance on it, and how the patient may revoke consent.	Technical and substantive changes to align with HIPAA. Because the CARES Act requires that revocations be in writing, there is no longer a requirement to honor oral revocations; however, HHS encourages entities to consider other civil rights implicated in oral interactions and to aid as needed to ensure meaningful access to affect a revocation.[42] HHS further clarifies in the commentary to the CARES Act Final Rule that revocation: (1) "does not require pulling back records that have been disclosed"[43]; and (2) programs are not required to notify consent recipients of subsequent revocations.[44] However, HHS emphasizes that "programs should convey to recipients . . . where feasible, when [a consent] has been revoked. This effort should include using whatever tools are at the disposal of the program to ensure that only consented information is exchanged."[45] HHS further provides that with respect

Current (42 CFR 2.31)	Final (42 CFR 2.31)	Summary of Change
		to HIN/HIEs: • "[W]hen an HIE/HIN learns of a patient's revocation of consent they would need to cease using or redisclosing the patient's Part 2 record to other entities.";[46] and • "Based on the public comments received, we also intend that when records have been transmitted through an HIE, the HIE should cease making further disclosures of the patient's record to other member participants."[47]
(7) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is provided.	(7) An expiration date or an expiration event that relates to the individual patient or the purpose of the use or disclosure. The statement "end of the treatment," "none," or similar language is sufficient if the consent is for a use or disclosure for treatment, payment, or health care operations. The statement "end of the research study" or similar language is sufficient if the consent is for a use or disclosure for research, including for the creation and maintenance of a research database or research repository.	Substantive changes to align with HIPAA and to allow for a TPO consent that does not expire.
(8) The signature of the patient and, when required for a patient who is a minor, the signature of an individual authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of an individual authorized to sign under § 2.15. Electronic signatures are permitted to the extent that they are not prohibited by any applicable law.	(8) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who has been adjudicated as lacking the capacity to make their own health care decisions or is deceased, the signature of a person authorized to sign under § 2.15. Electronic signatures are permitted to the extent that they are not prohibited by any applicable law.	Technical changes, including clarification that if someone other than the adult patient signs the consent form, the patient must have been adjudicated as lacking the capacity to make their own health care decisions.
(9) The date on which the consent is signed.	(9) The date on which the consent is signed.	No change.

Current (42 CFR 2.31)	Final (42 CFR 2.31)	Summary of Change
N/A	(10) A patient's written consent to use or disclose records for treatment, payment, or health care operations must include all of the following statements: (i) The potential for the records used or disclosed pursuant to the consent to be subject to redisclosure by the recipient and no longer protected by this part. (ii) The consequences to the patient of a refusal to sign the consent.	Substantive change. Additional content must be added to a TPO consent to provide the patient with notice of: (1) the downstream uses and redisclosures of the Part 2 record; and (2) if refusal to sign the TPO will have consequences, such as conditioning treatment or payment for treatment on the TPO consent. Contrary to statements made by HHS during a February 9, 2024 public webinar,[48] the CARES Act Final Rule expressly permits Part 2 programs and other lawful holders of Part 2 records to condition the provision of treatment on a patient signing a TPO consent. However, HHS does "believe a program should not condition treatment on a TPO consent unless it has taken reasonable steps to establish a workable process to address patients' requests for restrictions on uses and disclosures for TPO."[49]
N/A	Section 2.31(b) creates special rules for SUD counseling notes.	In the CARES Act Final Rule, HHS elected to create additional consent requirements (and exceptions to the consent requirement) for the use and disclosure of SUD counseling notes, which are separately discussed below.
N/A	Patient 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.	Substantive change. In the CARES Act Final Rule, HHS prohibits combining a consent to use and disclose Part 2 records against a patient in a proceeding with a consent to use or disclose the Part 2 record for any other purpose.

Heightened Protections for SUD Counseling Notes (42 CFR 2.31(b))

In the CARES Act Final Rule, HHS elected to adopt a definition of SUD counseling notes (see above) and to apply heightened privacy requirements for the use and disclosure of SUD counseling notes, similar to HIPAA's heightened

protections for "psychotherapy notes."[50] Except in limited circumstances, the CARES Act Final Rule requires a separate consent for the use and disclosure of SUD counseling notes, which cannot be combined with another type of consent.[51] In addition, a Part 2 program may not condition the provision to a patient of treatment, payment, enrollment in a health plan, or eligibility for benefits on the provision of a written consent for a use or disclosure of SUD counseling notes.[52]

Notice to Accompany Disclosure and Accompanying Consent/Consent Explanation (42 CFR 2.32)

HHS finalized the requirement that "each disclosure" of Part 2 records made with the patient's "consent" must be accompanied by the prescribed short form or long form of the prohibition on redisclosure notice, each of which has been updated in the CARES Act Final Rule. HHS has also rebranded the "prohibition on redisclosure notice" as the "notice to accompany disclosure."

HHS further added to the notice requirement a new requirement to transmit a copy of the patient's consent or clear explanation of the scope of consent with "each disclosure." HHS added this procedural requirement to enable Part 2 record recipients that are HIPAA regulated entities to identify whether the Part 2 records were disclosed pursuant to a TPO consent (and thus qualify for redisclosure for HIPAA-permitted purposes, except in proceedings against the patient) or something less/different than a TPO consent.[53] The consent (or consent explanation) may be combined with the notice to accompany disclosure.[54]

For the reasons discussed in greater detail below, it is not entirely clear whether and when HIPAA regulated entities that disclose or redisclose Part 2 records for HIPAA permitted purposes pursuant to the patient's underlying TPO consent are required to satisfy the notice and consent/consent explanation requirement. It may be that it is required for direct disclosures pursuant to a TPO consent obtained by a HIPAA regulated entity, but not for downstream redisclosures for HIPAA-permitted purposes by HIPAA regulated entity recipients of Part 2 program records. Because drawing such a distinction is most likely unworkable for HIPAA regulated entities, it may be necessary to comply with this provision even if it might not technically apply to every disclosure of Part 2 records.

HHS rejected commentators' concerns that keeping the notice requirement and adding to it the requirement to transmit a copy of the consent or explanation of the consent would effectively require continued Part 2 record data segmentation and segregation and may be technically infeasible for many (if not most) electronic systems. HHS offered this explanation in response:

> We do not believe that the notice requirement in § 2.32 is what may prompt segmentation of records or segregation of Part 2 data. . . . [W]e are finalizing additional modifications to § 2.12(d)(2)(i)(C) to expressly state that "[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." . . . . We believe health IT vendors are capable of updating or creating systems that manage consent, revocation, and other limitations on disclosure and redisclosure so long as the users of the system have current knowledge of the type of data and the limitations on its use and disclosure. The final rule neither requires nor prohibits segregation of records or segmentation of data to accomplish these tasks.[55]

Unfortunately, stating that data segregation or segmentation is not required does not change the fact that to meaningfully operationalize these requirements it is necessary to identify (that is, segment) the Part 2 records.

New Consent-Based Redisclosure Rules for Recipients of Part 2 Records (42 CFR 2.33(b))

The CARES Act Final Rule creates several categories of consent-based ***redisclosure*** rules based on the ***type of consent*** and the ***type of consent-recipient***:

(1) **TPO consent disclosures to HIPAA regulated entity recipients (42 CFR 2.33(b)(1)).** TPO consent recipients that are HIPAA regulated entities may "further disclose" Part 2 program records for any purpose permitted by HIPAA, except for uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient. HHS interprets the redisclosure permissions as being limited to recipients that are HIPAA regulated entities and excluding Part 2 program recipients that are not HIPAA covered entities or business associates.[56] HHS further explains that a Part 2 program that is a HIPAA regulated entity cannot use a TPO consent to disclose its Part 2 program records to itself to take advantage of the HIPAA permitted redisclosure permissions.[57]

In the CARES Act Final Rule, HHS also chose to delete language that would give HIPAA regulated recipients permission to "use" the Part 2 records for these purposes and limits the permissions to "further disclosures" of Part 2 records. HHS explains it did this to "more closely align with the statutory language." [58] HHS did not mention the substantive impact the change might have on what HIPAA regulated recipients can do with Part 2 records internally given Part 2's new definition of, and distinction between, "use" and "disclosure." Under revised Section 2.11, these terms have the following legal meanings:

- "Use means, with respect to records, the sharing, employment, application, utilization, examination, or analysis of the information contained in such records that occurs either ***within an entity*** that maintains such information or in the course of civil, criminal, administrative, or legislative proceedings as described at 42 U.S.C. 290dd-2(c)." (Emphasis added).

- "Disclose means to communicate any information identifying a patient as being or having been diagnosed with a substance use disorder, having or having had a substance use disorder, or being or having been referred for treatment of a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person."

HHS' deletion of the permission to "use" the Part 2 record for any purpose permitted by HIPAA may mean that for internal uses of the Part 2 record pursuant to a TPO consent, HIPAA regulated entity recipients may only ***use*** the Part 2 record internally for TPO purposes as permitted by HIPAA and not for other HIPAA permitted purposes (please see the section on TPO Consent). However, this might not be HHS' intended result given that it did not adopt HIPAA's definition of "disclosure." That is, the Part 2 definition of "disclosure" does not explicitly limit disclosures to those communications that occur outside of an entity.

(2) **TPO consent disclosures to Part 2 program recipients who are not HIPAA regulated entities (42 CFR 2.33(b)(2)).** Section 2.33(b)(2) provides that: "When disclosed with consent given once for all future treatment, payment, and health care operations activities 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." The recipient in this sentence is presumably the Part 2 program, and the Part 2 program presumably can further disclose the Part 2 record for TPO purposes under Part 2, which would require the patient's consent, unless an exception applies.

(3) **TPO consent disclosures to other lawful holder recipients who are not HIPAA regulated entities (42 CFR 2.33(b)(3) and (c)).** The revised Section 2.33 does not fully address whether or to what extent other lawful holders that are neither HIPAA regulated entities nor Part 2 programs—such as behavioral health providers that do not accept insurance—may be full TPO consent recipients. Presumably, such recipients could use and disclose the Part 2 record consistent with the TPO consent (*i.e.*, for TPO purposes under Part 2) and are not prohibited from using the Part 2 record to treat the patient, if the patient consented to use of the Part 2 record by them for treatment purposes. Indeed, HHS clarified in the commentary to the CARES Act Final Rule that:

"paragraph (b)(3) applies in situations where the written consent is only for payment and/or health care operations and does not include treatment."[59] In those instances, the recipient may further redisclose to 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. Such other lawful holders (that are not HIPAA regulated entities) must further comply with the requirement in Section 2.33(c) to have a written agreement in place with their contractors, subcontractors, and legal representatives, and to provide the required prohibition on redisclosure notice to them. Additionally, such contractors, subcontractors and legal representative cannot use the Part 2 record for treatment purposes (unless there is a consent or exception that authorizes it).[60]

(4) **Other non-TPO consent-based disclosures to any recipient.** Section 2.33 does not fully address whether or to what extent Part 2 programs, HIPAA regulated entities, QSOs, intermediaries, and other lawful holders may use and disclose the Part 2 record pursuant to Part 2-compliant consents for other purposes (that is, non-TPO consents). Presumably, such recipients may use and disclose the Part 2 record consistent with the consent and Part 2 requirements (*i.e.*, for the purposes stated in the consent and subject to Part 2 use and disclosure requirements).

Importantly, HHS interprets these redisclosure permissions in Section 2.33(b) as applying to ***recipients*** only—that is, persons other than the entity (such as the Part 2 program) making the disclosure. HHS explains:

> We interpret the broader HIPAA redisclosure permission to apply only to the recipient. Thus, a Part 2 program that obtains a TPO consent is limited to using or disclosing the record for TPO purposes [in Section 2.33(a)]—it cannot obtain a TPO consent and "disclose" the records to itself to trigger the permission to redisclose according to the HIPAA regulations and avoid overall compliance with Part 2. We believe that a disclosure implies a recipient other than the entity making the disclosure and the only recipients authorized by the statute to redisclose records according to the HIPAA regulations are those that are otherwise subject to HIPAA, which are covered entities (including those that are also Part 2 programs), and business associates."[61]

It is unclear how this applies to single legal entities—such as a health system—that operate Part 2 and non-Part 2 programs (often referred to as "Mixed Use Facilities"). Presumably, because the single legal entity does not "disclose" the Part 2 records to itself (as HHS is interpreting that term in the commentary to the CARES Act Final Rule), such Mixed Use Facilities will not benefit from the HIPAA redisclosure permissions, even if a patient signs a TPO consent authorizing the legal entity to share the Part 2 record with the entity's primary care physicians, for example. However, such a result will undercut the purported benefit of the Part 2 rule changes because such Mixed Use Facilities, which often use a single EHR, will continue to have to lock down their entire EHR due to data segmentation infeasibility issues (*e.g.*, the inability to segment the Part 2 record from the non-Part 2 record). This result is also contrary to Part 2's broad definition of "disclosure," which unlike HIPAA, is not limited to the external release of information.[62] HHS is aware of the uncertainty on this issue and has informally stated that it plans to issue guidance on this issue in the future.

Additionally, although the CARES Act and revised regulations permit HIPAA regulated entity recipients to use and redisclose the Part 2 record for any HIPAA-permitted purpose, the Part 2 regulations continue to apply to the Part 2 record maintained by those recipients,[63] and certain Part 2 requirements and obligations continue to apply. For example, in the commentary to the CARES Act Final Rule, HHS explains that if a HIPAA authorization is needed for any subsequent use or disclosure of the Part 2 program record, the HIPAA authorization must specifically authorize the disclosure of the SUD records. A general statement authorizing the disclosure of "my medical records" will not be sufficient to authorize the redisclosure of Part 2 records.[64]

Moreover, HHS revised its initial interpretation in the CARES Act Proposed Rule regarding the effect of a TPO revocation on consent recipients, to require such recipients to cease making further uses or disclosure of a Part 2 record once informed of a TPO consent revocation. HHS explains:

> Certain recipients under a consent for TPO (Part 2 programs, covered entities, and business associates) are permitted to redisclose records according to the HIPAA regulations. Under 45 CFR 164.508(b)(5) a covered entity or business associate is required to cease making further uses and disclosures of PHI received once they are informed of an authorization revocation, except to the extent they have already taken action in reliance on the authorization or if it was obtained as a condition of obtaining insurance coverage and other law provides the insurer with the right to contest a claim. We believe this requirement applies equally to revocation of a Part 2 consent. This interpretation is revised from the NPRM preamble discussion that proposed a revocation would only be effective to prohibit further disclosures by a program and would not prevent a recipient Part 2 program, covered entity, or business associate from using the record for TPO, or redisclosing the record as permitted by the HIPAA Privacy Rule.
>
> Taking into account covered entities' obligations under HIPAA once they are informed of a revocation, we believe they are also obligated to comply with a revoked consent about which they are aware. We do not see a reason for a recipient covered entity to treat a patient's revocation of Part 2 consent differently tha[n] a revoked HIPAA authorization. For example, if a Part 2 program disclosed Part 2 records under a TPO consent to a health plan and the patient later revoked said consent, the health plan that is processing a claim may complete the transaction but may not process new Part 2 claims for that patient/plan member. In another example, a covered entity health care provider who is currently treating a patient and has received a patient's Part 2 records will necessarily need to continue relying on the records it received to continue treating the patient (*e.g.*, the provider cannot "unlearn" the patient's history); however, it is prohibited from redisclosing the records once the patient revokes consent in writing. Handling revoked authorizations is not a new process for covered entities and they should therefore be capable of handling revoked consents in the same manner.[65]

It is also unclear whether HIPAA regulated entity ***recipients*** that receive Part 2 records pursuant to a TPO consent are required to provide the prohibition on redisclosure and accompanying consent (or summary of consent), see above, with each subsequent redisclosure of the Part 2 record. HHS makes seemingly conflicting statements in the commentary to the CARES Act Final Rule. On the one hand, HHS writes:

- "We further recognize that the notice is required only for disclosures made with consent, and **thus the notice would not be required for redisclosures as permitted by HIPAA for TPO or other permitted purposes when the initial disclosure was based on a TPO consent**."[66]

But on the other hand, HHS explains:

- "**We believe that the notice remains applicable to redisclosures by Part 2 programs, covered entities, and business associates** to operationalize the continuing prohibition on use and disclosure of Part 2 records in proceedings against the patient, which applies to redisclosures by recipients under § 2.12(d)."[67]

- "The introductory sentence of paragraph (a) of § 2.32 applies to each disclosure made with the patient's written consent, which includes the TPO consent finalized in this rule. . . . . Congress could have amended Part 2 to strike

entirely the regulatory Notice to Accompany Disclosure or removed the consent requirement for disclosures to programs, covered entities, and business associates, but it did not do so; instead, Congress mandated a modified version of consent. Therefore, **we interpret the existing requirement of a notice that accompanies each disclosure to apply to disclosures under a TPO consent in the same manner as for other disclosures with consent**."[68]

- "[**A]ll HIEs that receive Part 2 records with consent (whether they are intermediaries or business associates) would need to provide the notice to accompany disclosure when redisclosing such records with consent**."[69]

- "Commenters asked, collectively, whether an HIE, covered entity, and business associate must attach the notice on Part 2 records being redisclosed in accordance with the HIPAA privacy regulations, such as in paragraph (a)(2): '42 CFR Part 2 prohibits unauthorized use or disclosure of these records.' RESPONSE. The existing introductory language of paragraph (a) applies the notice requirement to '[e]ach disclosure made with the patient's written consent.' The abbreviated notice under paragraph (a)(2) was primarily intended to support EHR systems. As the Department explained in 2018, 'SAMHSA has adopted an abbreviated notice that is 80 characters long to fit in standard free-text space within health care electronic systems.' Though the notice under paragraph (a)(2) has been modified in this final rule to include the word 'use,' it remains largely as adopted in 2018. At that time the Department also said that it 'encourages Part 2 programs and other lawful holders using the abbreviated notice to discuss the requirements with those to whom they disclose patient identifying information.' An HIE may elect to use the abbreviated notice under paragraph (a)(2) or can choose to use one of the notices permitted under paragraph (a)(1). Covered entities and business associates are referenced in § 2.32(a)(1)."[70]

It could be that HHS is drawing a distinction between: (1) Part 2 record disclosures made pursuant to a TPO consent obtained by a HIPAA regulated entity under 42 CFR 2.33(a); and (2) downstream redisclosures of Part 2 records made pursuant to a TPO consent obtained by a person who disclosed the Part 2 records to the HIPAA regulated entity, see 42 CFR 2.33(b). That is, the notice and consent/consent summary may be required if the HIPAA regulated entity that obtained the TPO consent is making the disclosure, but not required if the HIPAA regulated entity received the Part 2 records pursuant to a TPO consent obtained by another person and is now engaging in a redisclosure of the received Part 2 records in accordance with HIPAA (that is, without an additional consent). However, such a distinction seems unworkable and contrary to the guidance above regarding HIN/HIEs. An HIN/HIE is typically not the entity that obtains the TPO consent, rather the HIN/HIE is the business associate that receives the Part 2 records pursuant to a TPO consent obtained by either the patient's Part 2 program, other provider or health plan. Thus, there is significant uncertainty in the regulations and guidance on when and whether the disclosure of Part 2 records pursuant to a TPO consent must be accompanied by the prohibition on redisclosure notice and copy of the consent or consent explanation.

Part Programs and Individual Rights

The CARES Act Final Rule also incorporates certain individual right requirements in Section 2.24 (Requirements for intermediaries), 2.25 (Accounting of disclosures) and 2.26 (Right to request privacy for protection for records).

Accounting Requirements for Part 2 Programs and Intermediaries (42 CFR 2.24 and 2.25)

The CARES Act Final Rule finalized requirements for intermediaries (which exclude HIPAA regulated entities) and Part 2 programs to provide certain accountings of disclosures to patients, upon request.

An "intermediary" is "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." Please see the section on Required Part 2 Consent Elements for more information on general designation consents. For non-HIPAA regulated intermediaries, under 42 CFR 2.24, they must provide to patients who have consented to the disclosure of their Part 2 records pursuant

to a general designation an accounting of disclosures made pursuant to that consent (up to 3 years prior to receipt of the request) if the patient submits a written request for such an accounting. Additionally, they must respond with such an accounting within thirty days or less and provide for each disclosure the name of the recipient entity, the date of disclosure, and brief description of the patient identifying information disclosed.

For Part 2 programs, under 42 CFR 2.25, they must provide to patients who have consented to a disclosure of their Part 2 records, an accounting of disclosures (up to 3 years prior to the date of the request) in accordance with the HIPAA requirements in 45 CFR 164.528(a)(2) and (b) through (d). This must include an accounting of TPO disclosures made through an electronic health record (EHR). However, HHS is tolling the compliance date for TPO accounting by Part 2 programs until HHS revises 45 CFR 164.528 to address accounting for TPO disclosures made through an EHR.[71] HHS has not tolled the accounting requirement for intermediaries.[72]

Restrictions on Disclosures (42 CFR 2.26)

HHS also finalized the rule change to add Section 2.26, which requires Part 2 programs to consider patient requests to restrict the use and disclosure of their Part 2 records for TPO purposes (even if the patient has signed a TPO consent) and to grant such a restriction if the restriction is on disclosures to a patient's health plan for services that the patient paid for in full. Section 2.26 also adopts HIPAA's requirements for terminating a previously granted restriction. Section 2.26 cannot be used to restrict disclosures required by law or permitted by Part 2 for purposes other than TPO.

At first blush, the inclusion of Section 2.26 and its language stating that a "Part 2 program is not required to agree to a restriction" (except for the self-pay restriction for health plans) is perplexing given that under Part 2's general consent requirement, a patient always controls whether or not their Part 2 records are used or disclosed for TPO purposes, unless an exception applies. That is, a patient that desires such restrictions could simply not give a TPO consent or issue a written revocation to a TPO consent previously given. We think the real significance of 42 CFR Part 2.26 is that it provides a process for patients to do the following:

- Request restrictions on the use and disclosure of their Part 2 records even in those limited circumstances in which Part 2 recognizes an exception to the consent requirement, such as disclosures without consent for medical emergencies. Indeed, Section 2.6 provides that if a Part 2 program grants a treatment restriction and then discloses information from the restricted record to a health care provider for emergency treatment under the medical emergency exception, the Part 2 program must request that the receiving health care provider not further use or disclose that information.

- Consent to TPO disclosures (especially in those circumstances where a Part 2 program may condition execution of a TPO consent on the provision of services), but request more granular restrictions on certain TPO disclosures, such as requesting that certain information not be shared with a certain health care provider or health plan. HHS explains:

> The renewed emphasis on the right to request restrictions on uses and disclosures of records for TPO is closely linked to the new permission to use and disclose records based on a single consent for all future TPO. We have stated in the discussion of the new consent permission that programs and covered entities that want to utilize the TPO consent mechanism should be prepared from a technical perspective to also afford patients their requested restrictions when it is otherwise reasonable to do so. Entities that are planning to benefit from streamlined transmission and integration of Part 2 records by using the single consent for all TPO should be prepared to ensure that patients' privacy also benefits from the use of health IT. . . . The final rule is emphasizing . . . that programs and covered entities are expected to do more than merely establish policies and

procedures on the right to request restrictions—they need to make a concerted effort to evaluate how they can reasonably accommodate patients' requests.[73]

HHS further states in the commentary to the CARES Act Final Rule that: "We believe that a program should not condition treatment on a TPO consent unless it has some capacity to fulfill patients' requests for restrictions on uses and disclosures for TPO…."[74] However, this same expectation under the revised Part 2 regulations does not apply to non-Part 2 programs, including other lawful holders of Part 2 records.

Prohibition on Use/Disclosure in Proceedings, Investigative Agencies and Court Orders (42 CFR Part 2, Subpart E)

The CARES Act Final Rule also expands upon existing prohibitions to more clearly and expansively prohibit the use and disclosure of Part 2 records in civil, criminal, administrative or legislative proceedings conducted by a federal, state, or local authority against a patient, absent a Part 2-compliant court order or patient consent. Those rule changes are primarily found in 42 CFR Part 2, Subpart E. For example, HHS finalized rule changes to clarify that the Subpart E requirements apply to civil, administrative or legislative proceedings (in addition to criminal proceedings) and protect testimony (in addition to patient records).

Miscellaneous

Definitions (42 CFR 2.11)

As noted through this briefing, the CARES Act Final Rule makes a number of changes to the Part 2 definitions. Specifically, the CARES Act Final Rule:

- Finalized the following definitions as proposed by the CARES Act Proposed Rule: "Breach," "Business associate," "Covered entity," "Health care operations," "HIPAA," "HIPAA regulations," "Informant," "Part 2 program director," "Patient," "Payment," "Person," "Program," "Public health authority," "Records," "Third-party payer," "Treating provider relationship," "Treatment," "Unsecured protected health information," "Unsecured record," and "Use";
- Added definitions of "Substance Use Disorder (SUD) counseling notes," "Lawful holder" and "Personal representative"; and
- Revised definitions of "Intermediary," "Investigative agency," "Patient identifying information" and "Qualified Service Organization" (QSO).

To the extent we thought these definitional changes made a substantive impact on Part 2 applicability or compliance obligations, we've covered those impacts elsewhere in this briefing.

Fundraising Opt Out (42 CFR 2.22 & 2.31)

The CARES Act Final Rule creates a new right for patients to opt out of receiving fundraising communications. A Part 2 program may use or disclose records to fundraise for its own benefit only if the patient is first provided with a clear and conspicuous opportunity to elect not to receive fundraising communications.[75] The Part 2 patient notice must include the right to elect not to receive fundraising communications.[76] If a Part 2 program intends to use or disclose records to fundraise on its own behalf, the Part 2-compliant consent must include a statement about the patient's right to elect not to receive any fundraising communications.[77]

Public Health Exception (42 CFR 2.54)

The CARES Act Final Rule finalized the "new" public health exception that allows for the disclosure of de-identified Part 2 records without patient consent for public health purposes. This change has no substantive impact on the law because Part 2 has always permitted the disclosure of de-identified Part 2 records for any purpose because Part 2 does not regulate the use or disclosure of de-identified information. The more significant change was HHS' adoption of the HIPAA de-identification standard for Part 2 (see the Part 2 De-Identification Standard). Prior to the CARES Act Final Rule, the

Part 2 de-identification standard permitted the use and disclosure of a HIPAA LDS (that is, a data set stripped of direct identifiers) subject to a DUA that prohibited re-identification of the individual who was the subject of the data set. This is no longer the case. Thus, individuals and organizations that are using LDS from Part 2 records for public health purposes will either need to fully de-identify those data sets pursuant to the HIPAA de-identification standard or obtain appropriate consents from patients.

No Data Segmentation Requirement

Throughout the CARES Act Final Rule, HHS repeatedly answers commentators' concerns that the changes do not go far enough to achieve Congress' intent to remove Part 2's barriers to integrated care and interoperability with the protest that they've updated the Part 2 regulations to expressly state that data segmentation and segregation is not required. To quote Shakespeare—"The lady doth protest too much, methinks." Part 2 has never legally mandated data segmentation and segregation. But the fact remains that to comply with the more stringent and onerous Part 2 data sharing requirements, it is necessary in health IT environments to identify Part 2 records and either: (1) segment/segregate the Part 2 records from less-protected records; or (2), due to data segmentation infeasibility, protect all the health information in the health IT system as protected by Part 2.

HHS acknowledges this reality by observing in the commentary that:

- "The final rule change expressly stating that data segmentation is not required by recipients under a TPO consent does not preclude the voluntary use of data segmentation or tracking as means to protect sensitive data from improper disclosure or redisclosure."[78]

- "Although we are finalizing a modification to § 2.12 to expressly state that '[a] 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[,]' some means to ensure that records are used and disclosed according to the scope of the consent will be needed."[79]

Disclosures to HHS

The CARES Act Final Rule amends Section 2.2 (Purpose and Effect) of the Part 2 regulations to require the disclosure of Part 2 records as required by the HHS Secretary to investigate or determine any person's—*i.e.*, a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private—compliance with Part 2. This is an important change because prior to it, there was no exception to the Part 2 consent requirement for HHS investigations. Unlike HIPAA, Part 2 does not have a "required by law" exception.

Antidiscrimination

You may have also noted that the CARES Act Final Rule does not address the CARES Act requirement that HHS implement regulations to prohibit discrimination against an individual based on their Part 2 records. HHS intends to address antidiscrimination in separate rule making.[80]

KEY TAKE-AWAYS FOR HEALTH CARE PROVIDERS, HEALTH PLANS AND HIN/HIEs

General Tips

Persons subject to Part 2 under the CARES Act Final Rule changes should work diligently over the next two years on their Part 2 compliance because enforcement is coming, and the regulatory, civil, and criminal liability risks are real. Individuals and organizations should also consider whether they want to opt for voluntary early compliance, including whether early compliance is feasible for the organization. Health care providers, health plans, HIN/HIEs and others

subject to Part 2 can implement effective Part 2 compliance plans by taking the following steps:

Step 1. **Identify Part 2 records as part of the organization's routine data mapping.** HIPAA regulated entities and entities subject to the Information Blocking Rule (IBR), CMS interoperability mandates, and/or state consumer data laws should already be conducting data mapping to support their regulatory compliance with these other health care and consumer data laws, as well as best security practices.

Step 2. **Identify the technical and administrative processes that can be used to tag and segment Part 2 records, including (if applicable) Part 2 records received pursuant to a TPO consent, Part 2 records received pursuant to a non-TPO consent, Part 2 records received pursuant to an exception, and SUD counseling records.** Although the Part 2 regulations do not mandate data segmentation and segregation, this step is necessary to ensure compliance with Part 2's more stringent privacy requirements. Moreover, because different data sharing rules apply depending on the type of Part 2 record (*e.g.*, SUD counseling note versus other Part 2 records), whether the Part 2 record was disclosed pursuant to a consent or an exception, and (if applicable) the type of consent obtained and whether the recipient is a HIPAA regulated entity (*i.e.*, a TPO consent versus a more limited or different Part 2 consent), organizations must further identify (tag) and segment the subsets of Part 2 records to ensure they are used and disclosed in compliance with the revised Part 2 regulations.

Step 3. **Identify and implement the technical and administrative processes necessary to apply the revised Part 2 data sharing rules to the Part 2 records maintained by the organization.** Organizations must operationalize the new requirement to transmit a copy of the Part 2 consent or summary of the Part 2 consent with each consent-based disclosure of Part 2 records. This is in addition to the existing requirement to transmit the prohibition on redisclosure notice with each consent-based disclosure of Part 2 records.

Step 4. **Update Part 2 consent forms and the prohibition on redisclosure notice and, if applicable to the organization, the Part 2 notice for patients and the HIPAA NPP.**

Step 5. **Update internal health information privacy policies and procedures to account for the organization's Part 2 compliance with respect to Part 2 records.**

The remainder of this section discusses "take aways" specific to Part 2 programs and health care providers, health plans, and HIN/HIEs.

Part 2 Programs and Health Care Providers

In addition to the general tips discussed above, Part 2 programs and health care providers should also be mindful of the additional nuances or requirements that might apply to them. This section highlights some of those considerations. **Please consult with your legal counsel to understand how the revised Part 2 regulations might affect you or your organization.** This briefing is intended for educational and information purposes only. It is not legal advice.

Part 2 Programs

Health care providers (and others) that operate Part 2 programs will need to take a closer look at the revised Part 2 regulations and adopt a more robust compliance program than their other lawful holder counterparts because many of the new requirements and obligations only apply to Part 2 programs. For example, the new breach reporting requirements, revised Part 2 notice (aka Part 2 summary) requirements, the opt out requirements for fundraising, and individual requested restrictions on disclosure provisions only apply to Part 2 programs. Additionally, Part 2 programs should carefully consider that their QSOs (and subcontractor QSOs) as well as other lawful holder recipients are not

required by Part 2 to report unauthorized uses and disclosures of Part 2 records in violation of Part 2 to individuals, HHS or others. This may affect how Part 2 programs choose to contract with their QSOs as well as with other lawful holders in data sharing arrangements.

Mixed Use Facilities

Health care provider entities that have a single corporate entity structure that operate both Part 2 programs and non-Part 2 programs, such as a HIPAA covered hospital that operates a chemical dependency unit, will need to assess whether and to what extent it can use TPO consents to remove historical barriers for achieving whole person care and participating in interoperability endeavors. For example, if the health care provider entity uses a single EHR, may that entity require TPO consents from its patients to disclose those Part 2 records to itself so that it may redisclose the Part 2 records to third-parties (such as a public health authority that participates in a HIN/HIE) for the full range of HIPAA-permitted purposes, excluding use or disclosure in proceedings against a patient?

Non-Part 2 Program Health Care Providers

In implementing new Part 2 compliance programs, non-Part 2 program health care providers who are other lawful holders of Part 2 records should not forget that the revised Part 2 regulations retain the applicability exception for such providers that document SUD information from the Part 2 program record in their non-Part 2 program record (see 42 CFR 2.11, definition of "record"). In those circumstances, the SUD information documented in the non-Part 2 program record is not considered a Part 2 record and is not protected by Part 2. Given the increased complexity with the different Part 2 data sharing rules that are dependent on the nature of the patient's consent, non-Part 2 program health care providers may want to consider whether its necessary to retain Part 2 records in their electronic systems or whether simply documenting the information from those Part 2 records used for their treatment of the patient is sufficient.

Health Plans

Health plans will continue to be other lawful holders of Part 2 records when they receive Part 2 records pursuant to: (1) written consent with the accompanying prohibition on redisclosure notice; or (2) pursuant to one of the exceptions to the written consent requirement (such as the audit or evaluation exception or as TPA of a group health plan under 42 CFR 2.33). Thus, they will continue to be subject to certain Part 2 obligations under the revised regulations. However, health plans will no longer be subject to Part 2's use and disclosure restrictions simply because they receive Part 2 records from Part 2 programs. Health plans may want to reassess, as part of the data mapping exercise, whether the SUD information they maintain in their systems are subject to Part 2.

Additionally, health plans should consider opportunities that might be available to structure their receipt of Part 2 records such that the Part 2 records in their systems are all maintained pursuant to a TPO consent. As a HIPAA regulated entity recipient of Part 2 records, a health plan may presumably redisclose the Part 2 records for the full range of HIPAA-permitted purposes (excluding uses or disclosures in proceedings against patients) when such records are received pursuant to a TPO consent. Because Part 2 does not prohibit the conditioning of treatment, payment, enrollment or eligibility on a patient executing a TPO consent, health plans may be able to require patients to sign, and/or health care providers to obtain, such TPO consents prior to disclosing the Part 2 record to the health plan. Whether this is permissible will likely depend on other federal or state laws applicable to the health plan and the health care providers responsible for collecting such TPO consents.

Finally, because health plans are HIPAA regulated entities that are now exempt from the Part 2 contracting requirements in 42 CFR 2.33(c), health plans should consider whether it is necessary (or if they desire to continue) including Part 2 contracting language in their written agreements with business associates that receive Part 2 records. To the extent a health plan is sharing Part 2 records with such business associates under the audit and evaluation exception, or in a QSO capacity for a Part 2 program, it may still be necessary to include certain legally required

contracting language in such agreements. However, there may be instances when specific Part 2 contracting language is no longer required.

HIN/HIEs

Like health plans, HIN/HIEs will continue to be other lawful holders of Part 2 records when they receive Part 2 records pursuant to: (1) written consent with the accompanying prohibition on redisclosure notice; or (2) pursuant to one of the exceptions to the written consent requirement (such as when HIN/HIEs receive Part 2 records as a QSO of Part 2 programs). Thus, HIN/HIEs that do not have the data system infrastructure and technical and administrative processes in place to manage the sharing of Part 2 records in compliance with Part 2's consent framework (including consent revocations) and/or exceptions (such as the medical emergency exception), should put into place contractual prohibitions and/or policies that prohibit data suppliers from making Part 2 records accessible through the HIN/HIE.

Fortunately, HHS' decision to exempt HIPAA regulated entities from the definition of "intermediary" and the relaxing of the Part 2 consent requirements to permit the general designation of consent recipients, makes it much more feasible for HIN/HIEs to design, build and implement Part 2 record sharing platforms. The more restrictive data sharing requirements applicable to intermediaries no longer apply to HIN/HIEs that are HIPAA business associates. Unfortunately, HIN/HIEs that offer Part 2 data sharing solutions will continue to need to identify, segment and suppress Part 2 records in order to operationalize HHS' decisions to:

- Require the display of the prohibition on redisclosure notice with each disclosure of Part 2 records;
- Require the transmission of the consent or clear explanation of the consent with each disclosure of Part 2 records; and
- Prohibit the continued redisclosure of Part 2 records through the HIN/HIE after consent has been revoked.

CONCLUSION

After nearly a decade of incremental changes to modernize Part 2 and align it with HIPAA to better serve individuals suffering from SUDs, the eagle has finally landed. The CARES Act Final Rule takes great steps in allowing patients to more broadly consent to the use and redisclosure of their Part 2 records by their health care providers and health plans so that these patients have a greater opportunity to leverage the benefits of whole person care and advancements in interoperability. Whether these benefits are realized will depend on whether health care providers, health plans, HIN/HIEs and their technology vendors are able to build the technology systems that are capable of identifying, segmenting, and segregating Part 2 records and deploying consent management functionality that meets the requirements of the Part 2 data sharing rules.

If you have questions or concerns about how the changes to the Part 2 regulations might affect your organization, please contact us at msoliz@cblawyers.com.

APPENDIX A: SUMMARY COMPARISON CHART OF THE CARES ACT PROPOSED RULE TO THE CARES ACT FINAL RULE

This chart contains a high-level summary of the material differences between the CARES Act Proposed Rule and CARES Act Final Rule. This chart does not contain a comprehensive of the differences between the CARES Proposed Rule and the CARES Act Final Rule. For a blackline comparison of the CARES Act Final Rule as compared to the CARES Act Proposed Rule please contact us at khyde@cblawyers.com.

Section	The CARES Act Proposed Rule	The CARES Act Final Rule
§ 2.3 Civil and criminal penalties for violations	**Safe Harbor Protection for Investigative Agencies.** The CARES Act Proposed Rule set forth certain measures an investigative agency must take to satisfy the "reasonable diligence" requirement for safe harbor protection against criminal or civil liability for the unauthorized use or disclosure of Part 2 records. **Enforcement.** The CARES Act Proposed Rule also provided that the HIPAA Enforcement Rule shall apply to Part 2 programs for violations of Part 2 without specific mention of such enforcement applying to other lawful holders or encompassing noncompliance (in addition to violations).	**Safe Harbor Protection for Investigative Agencies.** The CARES Act Final Rule clarifies and strengthens the measures that must be met to meet the "reasonable diligence requirement," by requiring the following to be done within 60 calendar days before requesting records or placing an undercover agent: • Search SAMHSA's SUD treatment facilities online record locator and any similar state database where the treatment facilities are located; • Check a provider's publicly available website (if available) or its physical location; and • View the provider's HIPAA NPP. **Enforcement.** The CARES Act Final Rule removed the "Part 2 program" limitation on application of the HIPAA Enforcement Rule enforcement in favor of clearly applying enforcement more generally to "noncompliance with this part."
§ 2.4 Complaints of noncompliance	**Complaints.** The CARES Act Proposed Rule provided that Part 2 programs must provide a process to receive complaints concerning the program's Part 2 compliance; that Part 2 programs may not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any patient for the exercise by the patient	**Complaints.** In addition to the revisions in the CARES Act Proposed Rule, the CARES Act Final Rule adds a right to file a complaint directly with the Secretary of HHS for an alleged violation of Part 2 in the same manner as filing a complaint for violation of HIPAA. Patients may also concurrently file a complaint with the Part 2 program.

Section	The CARES Act Proposed Rule	The CARES Act Final Rule
	of any right established, or for participation in any process provided for, by this part, including the filing of a complaint; and that Part 2 programs may not require patients to waive their right to file a complaint as a condition of the provision of treatment, payment, enrollment, or eligibility for any program subject to this part.	
§ 2.11 Definitions	**Definitions**. The CARES Act Proposed Rule added definitions for "Breach," "Business associate," "Covered entity," "Health care operations," "HIPAA," and "HIPAA regulations," "Intermediary," "Investigative agency," "Payment," "Public health authority," "Unsecured protected health information," "Unsecured record," and "Use." The CARES Act Proposed Rule revised the introductory text in the definition of "Informant," and revised the definitions of "Part 2 Program director," "Patient," "Person," "Program," "Qualified service organization," "Records," "Third-party payer," "Treating provider relationship," and "Treatment."	**Definitions**. In addition to the new and revised definitions included in the CARES Act Proposed Rule, the CARES Act Final Rule also added definitions for "Lawful holder," "Personal representative," and "SUD counselling notes." The CARES Act Final Rule also revised the definitions of "Intermediary," "Investigative agency," "Patient identifying information" and "Qualified Service Organization" (QSO). • The CARES Act Final Rule's definition of "**Intermediary**" is 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. This change from the definition in the CARES Act Proposed Rule will make sharing or accessing Part 2 records with or from HIEs that are operated by covered entities and/or business associates and set up for Part 2 data sharing much easier and less administratively burdensome. • The CARES Act Final Rule's definition of "**Investigative agency**" is "a Federal, state, Tribal, territorial, or local administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the activities of a part 2 program or other person holding records under this part."

Section	The CARES Act Proposed Rule	The CARES Act Final Rule
		• The CARES Act Final Rule's definition of "**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; (2) One of the exceptions to the written consent requirements in 42 U.S.C. 290dd-2 or this part." • The definition of "**Patient identifying information**" was changed to "the name, address, Social Security number, fingerprints, photograph, or similar information by which the identity of a patient, as defined in this section, can be determined with reasonable accuracy either directly or by reference to other information." • The CARES Act Final Rule's definition of "**Personal representative**" is "a person who has authority under applicable law to act on behalf of a patient who is an adult or an emancipated minor in making decisions related to health care. Within this part, a personal representative would have authority only with respect to patient records relevant to such personal representation." • The CARES Act Final Rule's definition of "**Qualified Service Organization**" is "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." This change from the definition in the CARES Act Proposed Rule clarifies that if an entity is the type of business associate that is performing HIPAA covered functions "on behalf of" a HIPAA covered entity, and that covered entity also operates a Part 2 program, that business

Section	The CARES Act Proposed Rule	The CARES Act Final Rule
		associate is also a QSO if they are getting PHI that constitutes Part 2 records. Importantly, however, QSOs are not required under Part 2 to report breaches of Part 2 records in violation of Part 2, even though the Part 2 program is required to report. • The CARES Act Final Rule's definition of "**SUD counselling notes**" is "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." This definition adopts the concept of SUD Counseling Notes (which mirrors the HIPAA definition of Psychology Notes).
§ 2.12 Applicability	**Segregation requirement.** The CARES Act Proposed Rule stated in pertinent part that: "(ii) Notwithstanding paragraph (d)(2)(i)(C) of this section, a non-Part 2 treating provider may record information about a substance use disorder and its treatment that identifies a patient. This is permitted and does not constitute a record that has been redisclosed under Part 2, <u>provided that any substance use disorder records received from a Part 2 program or other lawful holder are segregated or segmented.</u>" (Emphasis added.)	**Express statement that segregating or segmenting Part 2 records is <u>not</u> required.** The CARES Act Final Rule states in pertinent part that: ". . . . 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 <u>is not required to segregate or segment such records</u>. (ii) Documentation of SUD treatment by providers who are not Part 2 programs. Notwithstanding paragraph (d)(2)(i)(C) of this section, a treating provider who is not subject to this

Section	The CARES Act Proposed Rule	The CARES Act Final Rule
		part may record information about a SUD and its treatment that identifies a patient. This is permitted and does not constitute a record that has been redisclosed under this part." (Emphasis added.)
§ 2.16(a)(2) Security for records and notification of breaches	N/A	**Exception for family, friends, and other informal caregivers.** The CARES Act Final Rule adds an exception stating that family, friends, and other informal caregivers who are lawful holders as defined in Part 2 are not required to comply with the security requirements in § 2.16(a).
§ 2.22 Notice to patients of Federal confidentiality requirements	**Fundraising**. The CARES Act Proposed Rule required opt-in consent to use or disclosure of records for purposes of fundraising: "(B) Records that a program, covered entity, or business associate intends to use or disclose to fundraise for the benefit of the program, covered entity, or business associate, may be used or disclosed only with your valid written consent that complies with the requirements of 42 CFR Part 2." **Patient rights.** The CARES Act Proposed Rule includes a list of patient rights that must be included in the notice.	**Fundraising.** HHS rejected the opt in consent requirement for fundraising communications. The CARES Act Final Rule requires a clear and conspicuous notice of the opportunity to ***opt out*** of the use or disclosure of records for purposes of fundraising: "(B) A Part 2 program may use or disclose records to fundraise for the benefit of the Part 2 program only if the patient is first provided with a clear and conspicuous opportunity to elect not to receive fundraising communications." **Patient rights.** The CARES Act Final Rule adds to the list of patient rights by including the right to a list of disclosures by an intermediary for the past 3 years as provided in § 2.24 and the right to elect not to receive fundraising communications by opting out, as described above. **HIPAA NPP**. Updates to the HIPAA NPP are not required as part of the CARES Act Final Rule; it will be part of HHS's other HIPAA-specific rule making.
§ 2.31 Consent requirements	**Fundraising**. In the CARES Act Proposed Rule, HHS	**Fundraising**. The CARES Act Final Rule rejected the opt in

Section	The CARES Act Proposed Rule	The CARES Act Final Rule
	proposed to require an opt in consent for the use or disclosure of records for purposes of fundraising. **SUD counseling notes**. HHS further requested comment on whether it should adopt the concept of SUD counseling notes that are subject to heightened privacy protections, including additional consent requirements.	approach for fundraising communications in favor of an opt out approach. If a Part 2 program intends to use or disclose records to fundraise on its own behalf, a written consent must include a statement about the patient's right to elect not to receive any fundraising communications. **SUD counseling notes.** The CARES Act Final Rule requires a separate patient consent for the use and disclosure of SUD counseling notes (a concept that mirrors HIPAA's psychotherapy notes). **Civil, criminal, administrative, or legislative proceedings**. The CARES Act Final Rule states that a patient consent for use and disclosure of records in civil, criminal, administrative, or legislative proceedings (or testimony relaying information contained in a record) cannot be combined with a consent to use and disclose a record for any other purpose.
§ 2.32(b) Notice and copy of consent to accompany disclosure	N/A	**Copy of consent or consent explanation**. The CARES Act Final Rule requires that each disclosure made with patient consent include a copy of the consent or a clear explanation of the scope of the consent.
§ 2.33 Uses and disclosures permitted with written consent	**TPO consents.** The CARES Act Proposed Rule added § 2.33(a) for the use of a single TPO consent for future TPO disclosures of Part 2 records. The CARES Act Proposed Rule further added § 2.33(b) to permit a recipient of records disclosed pursuant to a written consent to further "use or disclose" such records in specified ways, including (1) when disclosed for TPO	**TPO consents.** The CARES Act Final Rule adds language to § 2.33(a) permitting the "use" of records pursuant to a TPO consent. The CARES Act Final Rule also adds the following language to § 2.33(a)(2), clarifying the permitted uses and disclosures of Part 2 records: "When the consent provided is a single consent for all future uses and disclosures for treatment, payment, and health care operations, a Part 2 program, covered entity, or business associate may use and disclose

Section	The CARES Act Proposed Rule	The CARES Act Final Rule
	activities to a covered entity or business associate (except for uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient), (2) when disclosed with consent given once for all future TPO activities to a Part 2 program that is not a HIPAA regulated entity, or (3) when disclosed for payment and health care operations activities to a lawful holder that is not a HIPAA regulated entity or Part 2 program.	those records for treatment, payment, and health care operations as permitted by the HIPAA regulations, until such time as the patient revokes such consent in writing." This provision requires a Part 2 program, covered entity, or business associate to honor a patient's written revocation even if the written consent was for all future uses and disclosures for TPO. The CARES Act Final Rule also revised the permissions in § 2.33(b) for recipients of Part 2 records by limiting its scope to "further disclosure" of Part 2 records and not the "use" of such Part 2 records.
§ 2.66(c)(3) Procedures and criteria for orders authorizing use and disclosure of records to investigate or prosecute a Part 2 program or the person holding the records.	N/A	**Court orders to obtain records**. The CARES Act Final Rule states that information from records obtained in violation of Part 2, including § 2.12(d), cannot be used in an application for a court order to obtain such records.
§ 2.67(c)(4) Orders authorizing the use of undercover agents and informants to investigate employees or agents of a Part 2 program in connection with a criminal matter.	N/A	**Court orders to obtain records**. The CARES Act Final Rule states that information from records obtained in violation of Part 2, including § 2.12(d), cannot be used in an application for a court order to obtain such records.

APPENDIX B: ADDITIONAL RESOURCES

Additional materials concerning the CARES Act Final Rule include:

- CARES Act Final Rule, 89 FR 12472 (Feb. 16, 2024)
- CARES Act Proposed Rule, 87 FR 74216 (Dec. 2, 2022)
- HHS, Press Release (Feb. 8, 2024)
- HHS, Fact Sheet 42 CFR CARES Act Final Rule

ABOUT THE AUTHORS

Melissa (Mel) A. Soliz, a partner with Coppersmith Brockelman, is highly sought out for her deep expertise on data privacy and interoperability issues ranging from HIPAA and 42 CFR Part 2 compliance to the ONC Information Blocking Rule, TEFCA (the Trusted Exchange Framework and Common Agreement), and CMS interoperability mandates, as well as deployment of artificial intelligence (AI) solutions (including generative AI using LLM). Her practice also focuses on health information exchange and networks, health IT contracting, data breaches and regulatory investigations, as well as clinical research compliance and contracting. Mel is President of the Arizona Society of Healthcare Attorneys (AzSHA) and is recognized by Chambers USA, Best Lawyers©, Southwest Super Lawyers: Rising Stars©, and Phoenix Magazine Top Lawyer for her work in health law.

Katherine Hyde advises clients in the health care industry on compliance with federal and state data privacy, security, and patient access laws, as well as data breach notification laws. She has experience developing policies and procedures for health care providers, drafting website privacy policies, analyzing uses and disclosures of health information to determine reporting obligations, and responding to subpoenas and other requests for health information. She also advises clients in the health care industry on communicating with patients and consumers and conducting digital advertising and marketing in compliance with state and federal laws.

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Check with your attorney for legal advice applicable to your situation.

ENDNOTES

[1] 89 FR 12472, 12482 (Feb. 16, 2024).
[2] 42 USC 290dd-2(a).
[3] *See generally* 42 CFR Part 2.
[4] HIPAA collectively refers to the Health Insurance Portability and Accountability Act and its implementing regulations, as amended from time to time.
[5] CARES Act, Pub. L. 116-136, 134 Stat. 281 (March 27, 2020) (as codified at 42 USC 209dd-2).
[6] 87 FR 74216 (Dec. 2, 2022).
[7] Throughout this brief we refer to HIPAA covered entities and business associates collectively as "HIPAA regulated entities."
[8] *See, e.g.*, 89 FR at 12485.
[9] *See, e.g.*, 89 FR at 12492.
[10] 89 FR at 12485.
[11] *See* 89 FR at 12490.
[12] 89 FR at 12619.
[13] 89 FR at 12618.
[14] 89 FR at 12631.
[15] 89 FR at 12496.
[16] HIPAA defines a "health plan" as: "an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).
(1) Health plan includes the following, singly or in combination:
(i) A group health plan, as defined in this section.
(ii) A health insurance issuer, as defined in this section.
(iii) An HMO, as defined in this section.
(iv) Part A or Part B of the Medicare program under title XVIII of the Act.
(v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, et seq.
(vi) The Voluntary Prescription Drug Benefit Program under Part D of title XVIII of the Act, 42 U.S.C. 1395w-101 through 1395w-152.
(vii) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).
(viii) An issuer of a long-term care policy, excluding a nursing home fixed indemnity policy.
(ix) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.
(x) The health care program for uniformed services under title 10 of the United States Code.
(xi) The veterans health care program under 38 U.S.C. chapter 17.
(xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.
(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, et seq.
(xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, et seq.
(xv) The Medicare Advantage program under Part C of title XVIII of the Act, 42 U.S.C. 1395w-21 through 1395w-28.
(xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.
(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).
(2) Health plan excludes:
(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1); and
(ii) A government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition):
(A) Whose principal purpose is other than providing, or paying the cost of, health care; or
(B) Whose principal activity is:
(1) The direct provision of health care to persons; or
(2) The making of grants to fund the direct provision of health care to persons." 45 CFR 160.103.
[17] 89 FR at 12620.

[18] 89 FR at 12509.
[19] 89 FR at 12619.
[20] 89 FR at 12499.
[21] 89 FR at 12490 ("We think it is more likely that the 'unknowing' situation could occur when an entity other than a part 2 program receives records without the Notice to Accompany Disclosure and rediscloses them in violation of this part because it is unaware that it possesses part 2 records. As we stated in the NPRM, we believe this scenario is addressed by the HITECH penalty tiers, so we are not expanding the safe harbor to other entities."); *see also id.* ("[T]he Department will consider the facts and circumstances and make a determination as to whether the disclosure of part 2 records warrants an enforcement action against the lawful holder. This would include considering application of the 'did not know' culpability tier for such violations.").
[22] 89 FR at 12503.
[23] 89 FR at 12504.
[24] 89 FR at 12504.
[25] 45 CFR 160.103; 45 CFR 164.514.
[26] *See* 42 CFR 2.11 ("Patient identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient, as defined in this section, can be determined with reasonable accuracy either directly or by reference to other information. The term does not include a number assigned to a patient by a part 2 program, for internal use only by the part 2 program, if that number does not consist of or contain numbers (such as a social security, or driver's license number) that could be used to identify a patient with reasonable accuracy from sources external to the part 2 program.").
[27] 42 CFR 2.16(a)(2) ("The part 2 program or other lawful holder of patient identifying information must have in place formal policies and procedures to reasonably protect against unauthorized uses and disclosures of patient identifying information and to protect against reasonably anticipated threats or hazards to the security of patient identifying information. These formal policies and procedures must address: . . . Electronic records, including: Rendering the patient identifying information non-identifiable in a manner that creates a very low risk of re-identification (e.g., removing direct identifiers).").
[28] 45 CFRR 164.514(e).
[29] 89 FR at 12566.
[30] 89 FR at 12556.
[31] 89 FR at 12545.
[32] HIPAA defines "psychotherapy notes" as "notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. Psychotherapy 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." 45 CFR 164.501.
[33] 89 FR at 12619-12620.
[34] 89 FR at 12620.
[35] 89 FR at 12528 .
[36] 89 FR at 12562.
[37] *See* 89 FR at 12544.
[38] 89 FR at 12543.
[39] 89 FR at 12545.
[40] 89 FR at 12546.
[41] 89 FR at 12546.
[42] 89 FR at 12553.
[43] 89 FR at 12552.
[44] 89 FR at 12552.
[45] 89 FR at 12552.
[46] 89 FR at 12552.
[47] 89 FR at 12553.
[48] During a February 9, 2024 public webinar, a HHS representative was asked: "May the programs condition treatment on a patient sending a consent to allow sharing information for treatment payment and healthcare operation?" Transcript, at 12:52:07. The HHS representative responded: "No." *Id.* at 12:52:15.
[49] 89 FR at 12546.

[50] Please see 45 CFR 164.508(a)(2) for HIPAA's heightened privacy requirements for the use and disclosure of psychotherapy notes.
[51] 89 FR at 12626.
[52] 89 FR at 12626.
[53] 89 FR at 12555.
[54] 89 FR at 12560.
[55] 89 FR at 12555.
[56] 89 FR at 12562.
[57] 89 FR at 12562.
[58] 89 FR at 12562.
[59] 89 FR at 12562.
[60] *See, e.g.*, 89 FR at 12560.
[61] 89 FR at 12562.
[62] HIPAA defines "disclose" to mean "the release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information." 45 CFR 160.103.
[63] *See* 89 FR at 12552.
[64] 89 FR at 12543.
[65] 89 FR at 12533.
[66] 89 FR at 12555 (emphasis added)
[67] 89 FR at 12554-55 (emphasis added).
[68] 89 FR at 12556 (emphasis added).
[69] 89 FR at 12556 (emphasis added).
[70] 89 FR at 12557 (internal footnotes omitted).
[71] 89 FR at 12537.
[72] 89 FR at 12534.
[73] 89 FR at 12538.
[74] 89 FR at 12541.
[75] 89 FR at 12624.
[76] 89 FR at 12624.
[77] 89 FR at 12626.
[78] 89 FR at 12513.
[79] 89 FR at 12559-60.
[80] 89 FR at 12579.