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HEALTH DATA SHARING AND PRIVACY

FACT SHEET

Confidentiality of Substance Use Patient Records: Key Provisions of The Notice of Proposed Rulemaking Changes to The Part 2 Rule

Complying with the federally mandated privacy provisions for the use and disclosure of substance use disorder (SUD) records under 42 CFR Part 2, particularly when those records are also protected by HIPAA, is often time-consuming and burdensome for those subject to those federal laws. People with an SUD have a right to those confidentiality protections, yet they and providers have often expressed frustration with the Part 2 Rule as its stringent requirements can impede care coordination and treatment. Responding to feedback to that effect, on December 2, 2022, the US Department of Health and Human Services published a Notice of Proposed Rulemaking to amend the Confidentiality of Substance Use Disorder Patient Records Rule (the "Part 2 Rule").

This Fact Sheet summarizes the key proposed provisions, identifies those which provide greater alignment with the HIPAA Rules, and calls out some areas on which HHS is specifically soliciting comments (due January 31, 2023). Of particular interest to the public health community, the Fact Sheet also presents the proposed changes to the data de-identification standard for disclosures of Part 2 data made to public health authorities.

SUMMARY[1]:

The overarching context for the proposed changes to 42 CFR Part 2 (the "Part 2 Rule")[2] is that Part 2 currently applies a different privacy standard for the use, disclosure, and protection of substance use disorder (SUD) records than the privacy standards set by the HIPAA (Health Information Portability and Accountability Act) Rules[3]. HIPAA and the HIPAA Rules cover a broader universe of health records than Part 2 and provide protections for health information that falls under the definition of

"protected health information" (PHI). This NPRM was prompted by the disjointed overlap of the two privacy standards when both Part 2 and HIPAA apply to SUD records. For providers and other entities subject to both Part 2 and HIPAA – and those who are not sure if they are – navigating the requirements of each to ensure compliance with both is confusing and time-consuming. That also has often slowed or impeded the sharing of PHI for care coordination and treatment purposes.

To resolve the confusion, the US Department of Health and Human Services (HHS) has issued a Notice of Proposed Rulemaking (NPRM) with three broad aims. First, the proposed rule would make the requirements for the use and disclosure of SUD records more straightforward to improve SUD treatment and care coordination. Second, the rule is designed to ease the burden of compliance on those entities subject to Part 2 or both Part 2 and the HIPAA Rules. Third, the Part 2 Rule should enhance the rights and privacy protections of individuals with SUD records. The proposed Part 2 revisions would better align the two regulatory schemes in two ways; the NPRM adopts and includes certain provisions of the HIPAA Privacy Rule and adds certain provisions of the HIPAA Breach and Enforcement Rules.

Implementing the proposed provisions would go a long way toward addressing many of the barriers to greater care coordination for people with SUDs. For example, providers would be able to use one consent form to cover both PHI generally and SUD records specifically. Further, that form can cover all future uses and disclosures of SUD records for treatment, payment, and operations (TPO) purposes. Also, the alignment of many key provisions would reduce the compliance burden with both Part 2 and the HIPAA Rules.

Another anticipated benefit is that the Rule would expand the instances when SUD records are protected from use and disclosure without a patient's consent. For example, patients' SUD records would now have protections in civil, administrative, and legislative (along with criminal) proceedings against them, removing a barrier to seeking treatment. Privacy protections would apply to both uses *and* disclosures, where the current regulatory language in most instances covers only one of those.

Public Health Specific Proposed Change An additional aim relevant to this public health audience is the proposed adoption in Part 2 of the HIPAA data de-identification standards for use and disclosure of data for public health purposes. The CARES Act, which was enacted in 2020 and from which flow these proposed rule changes, allows de-identified Part 2 (SUD) records to be disclosed to public health authorities without the patient's consent, adopting the HIPAA safe harbor and expert determination methods for data de-identification.[4] The proposed provisions would incorporate this CARES Act permitted disclosure of de-identified information to public health[5]

EFFECTIVE DATES: The proposed effective date for the final rule would be 60 days after publication and the compliance date would be 22 months after the effective date (24 months total), pushing compliance to no earlier than mid-2025. Further, as this Part 2 proposed rule would adopt the HIPAA accounting of disclosures standard in the Privacy Rule, which HHS has indicated in the NPRM that it intends to propose an amendment to, HHS is proposing to toll the compliance date of that standard for Part 2 programs until the effective date for the final rule of the Privacy Rule. (That ensures that

Part 2 programs do not become subject to compliance before covered entities and business associates do under HIPAA.)

NOTABLE HIGHLIGHTS OF THE PART 2 NPRM:

- Extends application of most Part 2 provisions to the use and disclosure of SUD records (the current rule generally uses only one of those terms).
- Adds new terms and definitions to align with HIPAA terms including:
    - Breach
    - Business associate
    - Covered entity
    - Health care operations
    - HIPAA regulations
    - Public health authority
    - Treatment
    - Unsecured protected health information, and
    - Use
- Creates new defined terms including Intermediary
- Modifies the Part 2 definitions of the following to distinguish them from and align them with similar terms in HIPAA:
    - Patient
    - Program
    - Records
    - Treating provider relationship, and
    - Qualified service organization
- Aligns the content requirements for Part 2 written consent to use or disclose Part 2 records with most of the content requirements for a valid HIPAA authorization.
- Clarifies how recipients may be designated in a consent to use and disclose Part 2 records for TPO, lightening the current rule's stringent requirement that recipients be specifically listed.
- While Part 2 would still require written consent for disclosures for TPO purposes, it would allow a single consent for all future uses and disclosures for TPO.
- Adds new patient rights to obtain an accounting of disclosures made with consent and to request restrictions on disclosures.
- Adds restrictions on the use and disclosure of records in civil, criminal, administrative and legislative proceedings against patients (current rule protections are limited to criminal proceedings).
- Permits Part 2 programs, like covered entities under HIPAA, to disclose de-identified records to public health authorities without need for patient consent.
- Adds civil money penalties for violations of Part 2 (same as HIPAA violations).
- Creates a limitation on civil and criminal liability (a safe harbor) for investigative agencies and person acting on their behalf that investigate and prosecute Part 2 programs (not patients) and unknowingly receive and disclose records subject to Part 2, provided certain conditions are met.

- Complaints of Part 2 violations would now be filed with HHS, not a U.S. Attorney.
- The definition of a Qualified Service Organization would be modified to include HIPAA business associates in circumstances when the Part 2 program is also a covered entity, adding clarity to what legal agreement would be needed between entities to use or disclose Part 2 records.
- The HIPAA Breach Notification Rule would now apply to Part 2.

THE NPRM'S SPECIFIC PROVISIONS THAT PROVIDE GREATER ALIGNMENT WITH THE HIPAA RULES:

1. §2.2 adds paragraph adapted from Privacy Rule specifying that nothing in Part 2 shall be construed to limit a patient's right to request restrictions on use of records for TPO or a covered entity's choice to obtain consent to use or disclose records for TPO purposes as provided in the Privacy Rule.
2. §2.3 applies the same civil and criminal penalties for violations of HIPAA to violations of Part 2 as implemented in the HIPAA Enforcement Rule.
3. §2.4 applies same HIPAA Privacy Rule requirements to Part 2 programs establishing a process to receive complaints, prohibiting adverse action against patients who file complaints, and prohibiting a requirement of individuals to waive the right to file a complaint as a condition of providing treatment, enrollment, payment, or eligibility for services.
4. §2.11 Several key definitions (*Breach, Business associate, Covered entity, Health care operations, HIPAA regulations, Public health authority, Treatment*) would now be the same under Part 2 and HIPAA. Other Part 2 terms *(Patient, Program, Records, Treating provider relationship, Qualified service organization*) would be modified to better clarify and distinguish them from similar terms under HIPAA.
5. §2.16 modifies the provision to more closely align with the HIPAA de-identification standard set in §164.514(b). Also, the HIPAA Breach Notification Rule would apply to breaches of unsecured records of Part 2 programs.
6. §2.22 modifies the Part 2 confidentiality notice requirements to align with the HIPAA Notice of Privacy Practices. Also, Part 2 programs and covered entities that receive Part 2 records from a Part 2 program would need to provide notice to individuals regarding privacy practices related to Part 2 records, including patients' rights and uses and disclosures that are permitted or required without authorization.
7. §2.24 and §2.25 would incorporate a patient's right to an accounting of certain disclosures that mirrors the Privacy Rule standard. It would also clarify what entities are "intermediaries" under Part 2 (e.g., Health Information Exchanges, care management organizations) to further facilitate the exchange of Part 2 records in new models of care. The obligations of intermediaries would not change other than extending the time period covered by the list of disclosures from two years to three.
8. New §2.26 would incorporate into Part 2 the same Privacy Rule rights of a patient to request restrictions on disclosures of records otherwise permitted for TPO purposes and to obtain restrictions on disclosures to health plans for services paid in full by the patient.

9. §2.31 would change the consent requirements, lighten the patient consent requirement for disclosures related to TPO by allowing a single consent from a patient that could include language authorizing all future uses and disclosures of their records for TPO purposes. It would also clarify under what circumstances a receiving party may further use or disclose records protected by Part 2.
10. §2.54 would permit Part 2 programs, like covered entities under HIPAA, to disclose de-identified records to public health authorities without patient consent and would better align with the HIPAA de-identification standards. It also clarifies that once de-identified for disclosure to public health authorities, Part 2 no longer applies to the de-identified Part 2 records.

HIGHLIGHTS OF PROPOSED RULE CHANGES THAT DO NOT EXPLICITLY TIE TO THE HIPAA RULES:

1. §2.3(b) would create a limitation on civil or criminal liability (a safe harbor) for persons acting on behalf of investigative agencies when, in the investigation of a Part 2 program or other person holding Part 2 records, they unknowingly receive Part 2 records without first obtaining the requisite court order and if they first acted with reasonable diligence to determine whether Part 2 applied to the records or program.
2. §2.19 adds an exception to clarify that the disposition of records by discontinued programs provisions do not apply to certain Part 2 programs pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA).
3. §2.63 would expressly add civil, administrative, and legislative proceedings to the currently included criminal proceedings as the matters for which a court order may be sought to permit or protect against the use or disclosure of Part 2 records. An example of when this may be needed is when a lawful holder of Part 2 records has been subpoenaed to produce the records and to withhold the records is to risk violating Part 2 and enforcement of the subpoena unless a judge rules on whether the records must be disclosed.
4. New §2.66 and §2.67 would create requirements for investigative agencies to follow if they discover in good faith that they have received Part 2 records before seeking a court order as required. Also, adds new criteria for issuance of a court order to permit the use or disclosure of the records when placement of an undercover agent or informant has already occurred.

AREAS IN NEED OF GREATER CLARITY FROM HHS:

What is not explicitly clear in the NPRM is whether the segregation of Part 2 records from other PHI in an entity's electronic records system, one of the most burdensome aspects of the different privacy protections under Part 2 and HIPAA, is no longer necessary to comply with all Part 2 provisions. A second issue is which agency within HHS will be tasked with investigations of any reported breaches and enforcement of penalties – SAMHSA or OCR?

SOME SECTIONS ON WHICH HHS IS SPECIFICALLY SOLICITING COMMENTS:

1. Its assumption that to the extent state laws address SUD records, Part 2 programs generally are able to comply with Part 2 and state law.
2. Examples of circumstances in which a state law compels a use or disclosure that is prohibited by Part 2, such that Part 2 preempts such state law. (See 87 Fed. Reg. 74234)
3. For future rulemaking, whether a safe harbor provision should be granted to providers that unknowingly hold Part 2 records and unknowingly disclose them in violation of Part 2. Related, HHS seeks comment on the impact of this proposed safe harbor to patient privacy and access to SUD treatment. (See 87 Fed. Reg. 74227)
4. Future rulemaking for "SUD Counseling Notes": HHS is considering whether to create a new definition like the one for psychotherapy notes that is specific to the notes of SUD counseling sessions by a Part 2 program professional. Such notes would be Part 2 records and could only be disclosed with a separate written consent that is not combined with a consent to disclose any other type of health information, with certain exceptions. (See 87 Fed. Reg. 74230)
5. The extent to which Part 2 programs look to the HIPAA Security Rule as a guide for safeguarding Part 2 electronic records and whether the same or similar safeguards requirements as apply to ePHI should apply to electronic Part 2 records. (See 87 Fed. Reg. 74233)

FUTURE RULEMAKING:

HHS must now update its Notice of Privacy Practices requirements to address the provisions regarding uses and disclosures of Part 2 records as contained in the NPRM, so proposed rulemaking will be forthcoming on the HIPAA Privacy Rule. HHS has stated that it will conduct separate rulemaking to implement the CARES Act antidiscrimination prohibitions.

[1] Note: Not all proposed provisions and amendments are covered in this summary. The contents of this summary are not being provided as legal advice and should not be relied upon as such. Please consult your attorney regarding the application of Part 2 or the HIPAA Rules to your work.

[2] The legal authority for the proposed rule changes comes from Section 3221 of the CARES (Coronavirus Aid, Relief, and Economic Security) Act, enacted in March 2020, which requires HHS to amend 42 CFR Part 2 and 45 CFR 154.520 to implement the proposed changes to 42 USC 290dd-2, the Confidentiality of Records section in the Public Health Service Act ("Part 2 statute").

[3] *See* the Privacy Rule, 45 CFR parts 160 and 164, subparts A and E; the Security Rule 45 CFR parts 160 and 164, subparts A and C; the Breach Notification Rule, 45 CFR part 164, subpart D; and the Enforcement Rule, 45 CFR part 160, subparts C, D, and E.

[4] The CARES Act adopted HIPAA de-identification standards in 45 CFR 164.514(b).

[5] Note, however, unlike HIPAA, neither the CARES Act nor Part 2 (current and proposed provisions) permit disclosure of identifiable information to a public health authority for public health purposes. Unlike HIPAA, Part 2 does not even allow disclosure of a limited data set for public health purposes. In short, the proposed provisions would do little to expand a health department's access to SUD information to carry out public health surveillance, investigation, and intervention.