United States Senate

WASHINGTON, DC 20510

February 14, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Attn: Office for Civil Rights (OCR), Director Melanie Fontes Rainer
Substance Abuse and Mental Health Services Administration (SAMHSA), Assistant Secretary for Mental Health and Substance Use, Miriam E. Delphin-Rittmon, Ph.D.

RE: Confidentiality of Substance Use Disorder (SUD) Patient Records Notice of Proposed Rulemaking (NPRM), Docket No. HHS-OCR-2022-0018

Dear Secretary Becerra,

We appreciate the opportunity to comment on the U.S. Department of Health and Human Services' (HHS) proposed rule on the "Confidentiality of Substance Use Disorder (SUD) Patient Records" through the Office for Civil Rights (OCR) and Substance Abuse and Mental Health Services Administration (SAMHSA). We understand the proposed rule is aimed at implementing the *Protecting Jessica Grubb's Legacy Act* (*Legacy Act*), which became federal law after it was included in the *Coronavirus Aid, Relief, and Economic Security Act* (*CARES Act*) (PL 116-136). As the sponsors and cosponsors of this law, we are pleased the proposed rule strives to reduce burdens to accessing care and enable more interoperability to share privacy records with the ultimate goal of reducing substance use disorder-related deaths.

Since the passage of the *Legacy Act*, the COVID-19 pandemic has continued to exacerbate the substance use crisis in the United States. According to recently published data, drug overdose deaths reached record levels in 2021; totaling nearly 107,000 people and reversing the progress that was made as recently as 2019.[1] As you know, the *Legacy Act* was enacted to reduce the burdens associated with accessing treatment, and better align the rule governing privacy records for patients with substance use disorder, known as *42 CFR Part 2* (Part 2) with the *Health Insurance Portability and Accountability Act* (HIPAA). Now, more than two years since the passage of the *Legacy Act*, it is important that we finalize this rule. This will allow us to improve care coordination, while protecting patient privacy, in order to ensure we are addressing the drug epidemic to our fullest potential

[1] Spencer MR, Miniño AM, Warner M. "Drug Overdose Deaths in the United States, 2001-2021," NCHS Data Brief No. 457, Dec. 2022, https://www.cdc.gov/nchs/products/databriefs/db457.htm#:~:text=Data%20from%20the%20National%20Vital,rates%20from%202020%20through%202021.

While we are pleased to see alignment with HIPAA on issues such as the definition of business associate, covered entity, breach and health care operations, we have concerns regarding ensuring there is clarity to reduce administrative burden and prevent unnecessary data segmentation. Please see our specific comments below.

Specific Comments

I. Segmentation of Part 2 Data

In our September 23, 2022 letter to the Office of Management and Budget Director Shalanda Young, we requested that this rule should "*Specify that once Part 2 data is transmitted or retransmitted with patient consent, there is no requirement to segregate a patient's Part 2 data from the rest of a HIPAA database*".[2] This proposed rule does not clearly eliminate the need to segment Part 2 data from HIPAA. The *Legacy Act* required a one-time initial written consent from the patient for information to be shared for purposes of treatment, payment, and health care operations (TPO).

The Notice of Proposed Rule Making (NPRM) states that "expanded ability to use and disclose Part 2 records would facilitate greater integration of SUD treatment information with other protected health information (PHI)." However, it is unclear how the proposed rule will help integrate Part 2 data with other systems and enable subsequent treatment providers access. It is important that once Part 2 data consent is received and transmitted to a covered entity or business associate, that there be no additional requirements for the data to be retained in a separate database.

II. Revocations

To ensure patient privacy protections, the *Legacy Act* required both a one-time initial written consent, and the ability for patients to revoke that consent. In our September 23, 2022 letter we clarified that this revocation must be in effect "*only from the point of revocation going forward.*"[3] We appreciate that the NPRM notes specially that revocation would be applied only from the point of revocation going forward. However, we would ask that HHS include intermediaries to be included in the list of entities where revocation of consent only affects additional disclosure. We believe this change would further clarify the intent of revocation. We also encourage HHS, OCR, and SAMHSA to offer subsequent guidance on the best way to flag a revocation within electronic health records that can help make this more seamless.

III. Intermediary/Business Associates

The NPRM proposes a definition for intermediary as "a person who has received records under a designation of general written patient consent to be disclosed to one or more of its member participants with a treating provider relationship with the patient." This definition could include

[2] Manchin, Joe, et al. (September 23, 2022). [Letter to Director Shalanda Young]
[3] Manchin, Joe, et al. (September 23, 2022). [Letter to Director Shalanda Young]

health information exchanges (HIEs), and researchers. The proposed rule also suggests distinct and separate limits on redisclosures based on prior consent for intermediaries. In our September 23, 2022 letter we specifically requested that the NPRM "*include specific language directing covered entities and business associates to disclose and redisclose data in accordance with HIPAA.*"[4] We are concerned that providing a definition of intermediary may cause confusion on disclosure and redisclosure as it relates to a business association or an intermediary. Therefore, we suggest either not specifying "intermediaries" under your definition, or clarifying that an "intermediary" is an individual or entity, not otherwise covered by the definition of "business associate."

IV. Technical Assistance of Part 2 Rule and Compliance Date

The NPRM states that the compliance date of the regulations would be 22 months after the effective date and 24 months after publication. While we understand that implementation of this rule will require impacted stakeholders adequate time to become familiar with these new changes, we would recommend robust technical assistance (TA) to help entities implement the rule sooner rather than later. Several stakeholders have noted as short a timeline as 10 months after the effective date. However, we understand the concerns with ensuring full compliance and implementing this NPRM.

Therefore, we encourage you to undertake technical assistance which could include, but is not limited to collaborations to create multiple learning modalities, including webinars, written sub-regulatory guidance, sample wording, and public awareness campaigns. We also encourage the tracking, monitoring, and sharing of lessons learned and best practices through implementing these Part 2 rule modifications so that all entities can continue to learn how to carry out these provisions best and enhance treatment delivery.

Conclusion

This NPRM is a significant step towards aligning Part 2 with HIPAA, and we appreciate your efforts towards implementing the *Legacy Act*. We hope that with some additional clarity, we will be able to meet the goals of reducing administrative burdens and ensuring certain providers will be able to share information confidently.

Sincerely,

Joe Manchin III
United States Senator

Shelley Moore Capito
United States Senator

[4] Manchin, Joe, et al. (September 23, 2022). [Letter to Director Shalanda Young]

Jeffrey A. Merkley
United States Senator

Amy Klobuchar
United States Senator

Susan M. Collins
United States Senator