

United States Senate

WASHINGTON, DC 20510

September 23, 2022

The Honorable Shalanda D. Young
Director
Office of Management and Budget
725 17th Street N.W.
Washington, D.C. 20503

Re: Review of *Confidentiality of Substance Use Disorder Patient Records* Proposed Rule

Dear Director Young,

We are writing to you regarding the proposed *Confidentiality of Substance Use Disorder Patient Records* rule pending review by your office. This 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 (CARES) Act (PL 116-136) during the 116th Congress. The Department of Health and Human Services submitted their proposed rule to implement this bill to your agency on September 7, 2022. As you review this rule, we wanted to clarify the bipartisan congressional intent underpinning the Legacy Act. We also want to urge a swift review, as it has been over two years since the passage of the Legacy Act.

Since the passage of the Legacy Act, the COVID-19 pandemic has exacerbated the substance use crisis in the United States. According to recently published data, more than 108,000 people lost their lives to overdose in 2021 reversing progress that was made as recently as 2019. After over two years the proposed rule is finally under your consideration.

Swiftly reviewing this proposed rule amending substance use disorder privacy laws would be helpful in reducing opioid use disorder (OUD) deaths. The measure more closely aligns federal privacy standards applicable to substance use disorder (SUD) patient records – with the objective of facilitating the sharing of critical medical information for the purposes of treatment, payment, and health care operations (TPO) as those terms are defined in the Health Insurance Portability and Accountability Act (HIPAA) while eliminating re-disclosure requirements.

As we noted in our letter dated March 24, 2021, to the Substance Abuse and Mental Health Services Administration (SAMHSA), the regulation implementing the Legacy Act – by amending 42 CFR Part 2 – must build on bipartisan congressional and regulatory actions. The intent of the legislation is to enhance care coordination for patients with OUD while helping mental health and substance use disorder providers share medical data with primary care physicians, acute care hospitals, and specialty medical practices. We stressed that HHS ensure that the regulation memorialize what is in the CARES Act as well as Congressional intent, especially as it relates to the eliminating re-disclosure requirements and simplifying the sharing of patient health information after obtaining consent employing existing HIPAA standards.

We urge you to issue this new rule and submit the following for your consideration:

- *Ensure that the consent requirements in the rule are simple and straightforward so additional administrative processes are not imposed on patients, providers, or payers (including health plans and their subcontractors). The consent process should be easily folded into existing HIPAA compliance processes, preferably with the patient's acknowledgement of HIPAA practices and the patient's Part 2 consent incorporated into the same document at intake where feasible. Furthermore, include language to address the conflict with Part 2's list of disclosures requirement.*
- *Include specific language directing covered entities and business associates to disclose and redisclose data in accordance with HIPAA regulations, provided a one-time initial consent is explicitly obtained from the patient.*
- *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, with the regulatory requirement for data segmentation terminating upon transmission or retransmission.*
- *Specifically state that the revocation of consent for Part 2 data transmission is effective only from the point of revocation going forward and that responsibility for the revocation should be limited to those who are so notified by the patient and their respective actions while preserving patients' ability to explicitly revoke consent retroactively should they so choose.*
- *Include a provision in the rule to ensure that disclosures for the purposes of research from a HIPAA covered entity to a non-HIPAA covered entity are permissible, consistent with existing HIPAA rules.*
- *Include specific language to ensure that patient privacy rights are protected in accordance with the CARES Act and HIPAA.*
- *HHS should be providing de-identified SUD-related claims data to providers practicing in alternative payment models to help support their work in population health management.*

We look forward to working with you closely as you review the *Confidentiality of Substance Use Disorder Patient Records* rule that fully complies with the Legacy Act. Thank you for your attention on this important matter.

Sincerely,



Joe Manchin III
United States Senator



Shelley Moore Capito
United States Senator



Bill Cassidy, M.D.
United States Senator



Jeffrey A. Merkley
United States Senator



Susan M. Collins
United States Senator



Thom Tillis
United States Senator



Amy Klobuchar
United States Senator

CC:
The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
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