January 31, 2023

Dr. Miriam E. Delphin-Rittmon
Substance Abuse and Mental Health Administration
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave, S.W.
Washington, DC 20201

Submitted electronically via Regulations.gov for HHS-OCR-2022-0018-0001

Re: Confidentiality of Substance Use Disorder Patient Records Proposed Rule

Dear Assistant Secretary Delphin-Rittmon,

On behalf of the Community Behavioral Health Association of Maryland (CBH), thank you for the opportunity to comment on the Confidentiality of Substance Use Disorder Patient Records, which aligns 42 C.F.R. Part 2 (hereinafter "Part 2") with the requirements under the Health Insurance Portability and Accountability Act (HIPAA). CBH is a membership organization representing over 100 community-based mental health and addiction treatment providers in Maryland. We advocate for policies to ensure equitable access to treatment where and when needed, and support our members in the delivery of high-quality services.

1. CBH supports the overall direction of this Proposed Rule.

As a leader in promoting health interoperability between our members and Maryland's health information exchange (HIE), CBH and its members have firsthand knowledge of the barriers the current Part 2 regulations place between patients, their clinicians, and the consented-exchange of their information. Under the current provisions of Part 2, added consent requirements and inconsistency in definitions result in data related to substance use disorder ("SUD") patients not being shared across the health care system. Without clarity on what data can be shared when, with whom and for what purpose, providers and organizations err on the conservative side and do not share their data. This causes a data gap that prevents providers and organizations from having a complete view of an individual. Those data gaps can impact the care received by an individual as providers are not aware of what other providers an individual is seeing, leading to disjointed care, incomplete care, or even inappropriate care.

In particular, the proposed changes to Part 2 would benefit our member organizations by reducing the administrative burden of staff having to get the patient to sign a separate release of information for the billing payer, each doctor, and family member that they wish to include. In our members' reported experience, most patients wish to coordinate their care among treatment providers. It is complex and challenging for providers to keep up with all of the separate releases needed to accomplish care coordination. Having the ability to get a single, multipurpose release and the ability to re-release would produce better, more informed care as well as relieve administrative burdens on an already taxed workforce.

We wholeheartedly support the overall vision of the Proposed Rule: a system where a patient can consent to their data being shared for any treatment, payment, or operations functions, as defined in the Health Insurance Portability and Accountability Act ("HIPAA"). However, as currently written, the regulations would impede the *electronic exchange* of data for purposes *other* than treatment, contrary to the intent not only of the 21st Century Cures Act (Cures Act), but also of the Proposed Rule, itself. Therefore, we urge SAHMSA to make the changes suggested below in the Final Rule.

2. SAMHSA should no longer separately regulate "intermediaries."

In the Proposed Rule, SAHMSA notes that it is providing a definition of "intermediary" because the current regulations lack such a definition (87 FR 74229). SAHMSA explicitly calls-out a "health information exchange" as an example of an "intermediary." Further, SAMHSA states that "intermediaries," such as HIEs, would have to comply with the requirements for both "intermediaries" and business associates if the Proposed Rule goes into effect. **Consequently, throughout the Proposed Rule, additional layers of burden without a resulting benefit, which would impede the electronic exchange of health information, are placed on intermediaries, include HIEs and RHICs. As we explain below, with the Cures Act, the construct of an "intermediary" is no longer necessary, the requirements for business associates effectively regulate these entities, and, therefore, SAHMSA should remove the idea and regulation of "intermediary" from the Final Rule entirely.**

Previous regulations used the term "intermediary" to explain the requirements for those receiving data under a general designation. This distinction was necessary because, without it, entities such as HIEs and others that promote interoperability and health information exchange could not comply with the Part 2 regulations in a way that was practicable – that is, it would be nearly impossible to give consent to every HIE or electronic health record (EHR) vendor acting as a conduit for information exchange between treating providers. Thus, this idea of a general designation and an "intermediary" were introduced to *promote* interoperability. ("SAMHSA has concluded that the proposed changes . . . would facilitate care coordination and information exchange." 82 FR 6084.)

With the CURES Act changes and the changes contemplated in the Proposed Rule, including the introduction of the definition "business associate," as used in HIPAA, the previous solution initiated by SAMHSA is no longer necessary. In fact, SAHMSA specifies requirements, including consent requirements for business associates in §2.31(a)(4)(iii), throughout the Proposed Rule. Therefore,

additionally regulating intermediaries is not only unnecessary, but would likely have the opposite effect as SAHMSA's original intent to "facilitate care coordination and information exchange."

For intermediaries—*and intermediaries only* (i.e., NOT business associates)—a general designation "must be limited to a participant who has a treating provider relationship with the patient whose information is being disclosed." (§2.31(a)(4)(ii)(B)). By retaining the intermediary construct, SAMHSA would create a tiered system of information exchange that would limit exchange via HIEs for purposes outside of the narrow "treating provider relationship" (as defined in the Proposed Rule), including limiting exchange for broader treatment purposes, such as care coordination, as "Treatment" is defined under HIPAA. We believe such a limitation is contrary to the intent of these proposed changes and inconsistent with current HHS policy regarding HIE participation in and the Exchange Purposes under the government's Trusted Exchange Framework and Common Agreement ("TEFCA"). This result is contrary not only to SAMHSA's expressed intent, but also to the language of the Cures Act. ("Once prior written consent of the patient has been obtained, such contents may be used or disclosed by a covered entity, business associate, or a program subject to this section for purposes of treatment, payment, and health care operations as permitted by the HIPAA regulations." 42 USC 290dd-2(b)(1)(B).)

Additionally, neither the Cures Act nor the original Part 2 statute define or reference "intermediaries" or otherwise require additional regulation for intermediaries. Again, this designation was crafted by SAMHSA to "facilitate care coordination and exchange of information," which is accomplished through the Cures Act changes and the accompanying Proposed Rule without the construct of an "intermediary."

We urge SAHMSA to finalize regulations that do not include the construct of "intermediaries." Alternatively, if SAMHSA believes independently regulating intermediaries is necessary, we urge SAMHSA to limit the definition of "intermediaries" to individuals/entities not otherwise covered by the definition of "business associate" in the Proposed Rule and HIPAA. This request is specifically important because, without doing so, SAHMSA would create additional requirements for business associates to perform account of disclosures (§2.24) which are not aligned with HIPAA. Business associates and covered entities already work together, as necessary, to provide such an accounting under HIPAA; this additional requirement would create unnecessary burden for business associates while not providing any additional information to the patient – the auditing process and the records audited would be identical.

3. **SAMHSA should permit public health authorities to receive identifiable data in the regulations.**

SAHMSA permits the disclosure of deidentified Part 2 data to public health authorities (§2.54), but does not explicitly allow identifiable data to be shared with public health authorities with patient consent. Our members working as Health Data Utilities ("HDUs") regularly navigate HIPAA and consent requirements to share critical health data with public health authorities. Specifically, some of our HDUs share overdose death information with local public health authorities so that they can provide appropriate follow-up and offer the necessary resources to those affected by SUD. Our

members have also experienced difficulty in producing public and population health information such as heat maps showing highest utilization of SUD facilities and open bed counts for the purpose of referrals.

We urge SAMHSA to adopt regulations that are aligned with HIPAA for public health authorities; SAHMSA should permit the disclosure of identifiable data to public health authorities with patient consent.

Thank you for the opportunity to provide feedback and for your continued commitment to improving interoperability and health information exchange. If you have questions, please do not hesitate to reach out to me at shannon@mdcbh.org.

Sincerely,

Shannon Hall
Executive Director