CIVITAS
Networks for Health

January 31, 2023

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: SUD Patient Records
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

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

Re: Confidentiality of Substance Use Disorder Patient Records Proposed Rule

Civitas Networks for Health ("Civitas"), appreciates the opportunity to provide input on the Confidentiality of Substance Use Disorder Patient Records Proposed Rule (the "Proposed Rule"). Civitas is a national collaborative of regional and statewide Health Information Exchanges ("HIEs") and Regional Healthcare Improvement Collaboratives ("RHICs"). We are significant stakeholders in the health data interoperability and health improvement landscape - helping providers, facilities, and other key collaborators achieve many of the policy goals presented in the above-mentioned Proposed Rule. Representing more than 95% of the United States, Civitas is comprised of over 160 member organizations working to use health information exchange, health data, and multi-stakeholder, cross-sector approaches to improve health. We educate, promote, and advocate to the private sector and policymakers on matters of interoperability, quality, coordination, health equity, access, and cost-effectiveness of healthcare. While there are many areas of this rule on which Civitas' work and stakeholders' expertise is applicable, we would specifically like to comment on the sections discussed below.

1. **Civitas supports the overall direction of this Proposed Rule; however, as currently written, we believe it could impede, rather than promote, the electronic exchange of data.**

As leaders in promoting and expanding health interoperability across the countries, our members possess first-hand knowledge of the barriers the current Part 2 regulations place between patients, their clinicians, and the consented-based 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 wholistic 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.

For example, in 2020, SYNCRONYS, the State of New Mexico's HIE received funding to enhance the HIE. The funding included resources to promote the exchange of data with the 19 Federally Qualified Health Centers ("FQHCs") representing 232 individual clinics located in New Mexico. Many of the FQHC facilities qualify as Part 2 facilities. All of the interfaces to exchange data are completed, but four of the FQHCs block all of their data from being shared, due to the additional requirements of Part 2.

Similarly, the Michigan Health Information Network ("MiHIN") and affiliated organization Velatura Health Information Exchange Corporation ("VHIEC"), have experienced segregation and siloed data due to incomplete guidance related to Part 2. Despite state-wide efforts and targeted technology, it has been an uphill battle to build the consensus and trust required to share Part 2 information. Regardless of the success the HIEs have seen sharing health information under HIPAA, information under Part 2 remains primarily siloed by Part 2 facilities because of hesitations and fear to share these data led to extremely conservative interpretations of Part 2.

We 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 Coronavirus Aid, Relief, and Economic Security ("CARES") Act, but also of the Proposed Rule, itself. Therefore, we urge SAMHSA to make the changes suggested below in the Final Rule.

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

In the Proposed Rule, SAMHSA notes that it is providing a definition of "intermediary" because the current regulations lack such a definition (87 FR 74229). SAMHSA 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 CARES Act, the construct of an "intermediary" is no longer necessary, the requirements for business associates effectively regulate these entities, and, therefore, SAMHSA 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 CARES 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, SAMHSA 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 SAMHSA'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 CARES 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 CARES 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 CARES Act changes and the accompanying Proposed Rule without the construct of an "intermediary."

We urge SAMHSA 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, SAMHSA would create additional requirements for business associates to perform an accounting 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 explicitly state that data do not need to be "clawed back" if a patient revokes consent.

In §2.31(a)(6) of the Proposed Rule, SAMHSA notes that a patient has the "right to revoke the consent in writing except to the extent that the part 2 program, or other lawful holder . . . permitted to make the disclosure, has already acted in reliance upon it . . . ." Traditionally, implementers of these regulations and their attorneys have interpreted the regulations in the most conservative way possible. Therefore, we are concerned that this provision could be read to argue that, if a patient withdraws consent, any data that have previously been disclosed could be "clawed back." We do not believe this is the intent of SAMHSA, nor would such an intent be practicable. If taking the most conservative approach and interpreting a revocation to imply that all information previously shared must be removed, it would not only prove burdensome and impractical, but it would also discourage information sharing for fear of later revocation. As a result, many may choose to forgo providing centralized data services. Furthermore, once the information has been utilized by the receiver, it is unclear if deletion after revocation would accomplish the initial intent.

We urge SAMHSA to affirmatively clarify that revocation of consent only applies to the use or disclosure of information *going forward* from the time of revocation.

4. SAMHSA should address not only healthcare, but social care in the Proposed Rule.

Increasingly, our members' work includes the vital exchange of social needs data from community-based organizations and community care hubs. These data treat the underlying causes and consequences of SUD, including housing and food insecurity, which are often best addressed outside the traditional healthcare system. Data exchange with and including organization that have traditionally been outside the scope of HIPAA treats the whole patient and breaks down the underlying systems of disparity and inequity.

Specifically, in addition to HIEs, SAMHSA should prioritize publishing comprehensive guidance, examples, and guardrails specific to how RHICs are able to advance the interoperable goals of sharing information protected by Part 2. These multi-stakeholder, nonprofit, neutral entities provide critical technical assistance related to health system, delivery system, and practice transformation improvements addressing population health, payment reform, quality improvement, patient safety, and health care affordability. While they have not received as much attention in Federal regulations, RHICs are referenced and supported through statewide initiatives to improve healthcare. **We suggest that SAMHSA explicitly address these non-HIPAA entities and a create a framework for consent-based data sharing with and between them in the Final Rule.**

5. Based on our members' experience with providers and data exchange, we believe that there may be additional areas of operational concern.

Specifically, SAMHSA proposes to include a definition of "SUD counseling notes," which would, as with psychotherapy notes under the Privacy Rule, protect these notes further from disclosure.

(87 FR 74230). It is our experience that many Part 2 providers are not resourced enough to segment their notes from the rest of the Part 2 record. Therefore, by adding this concept of "SUD counseling notes," Part 2 providers may not share their records, in general. Because the burden of segmentation would be too high, the entire record would become subject to limitations for further disclosure, effectively negating the remainder of the Proposed Rule and the intent of the CURES Act.

Additionally, we note that the notice requirements in §2.22 are cumbersome and overly detailed. These requirements may be confusing to providers and patients alike and result in a greater number of patients withholding consent due to their lack of understanding. The requirements should be clarified and shortened to no more than one page, and the required notice language should be written at a fifth-grade reading level. **We request that, if adopted, SAMHSA provide educational materials and templates for providers and work with patient advocates to ensure the §2.22 notice requirements are understandable to patients and practical and operational for providers.**

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

SAMHSA permits the disclosure of deidentified Part 2 data to public health authorities (§2.54), but it does not explicitly allow identifiable data to be shared with public health authorities with patient consent. Our members working as Health Data Utilities ("HDUs")[1] 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; SAMHSA should permit the disclosure of identifiable data to public health authorities with patient consent.

7. SAMHSA should expedite the effective date of the regulations and more closely align the effective date with the compliance date.

SAMHSA states that the compliance date of the regulations would be 24 months (effective date plus 22 months) after the final rule is published. (87 FR 74218). We understand that it may take providers an extended period to implement these changes with their EHR vendors. That said, we think this timeline may be excessive, and we ask that SAMHSA enforce a compliance date that is as soon as possible.

[1] *See* https://www.civitasforhealth.org/wp-content/uploads/2022/12/Civitas-MHCC-HDU-Brief_FINAL_2022-15-12.pdf.

In addition, this proposal seems to envision a period of 22 months where entities could decide which rules (the old or new) to follow. Such a proposition would be incredibly complicated and would impede interoperability, as providers and business associates, alike, would have to manage two consent processes based on which set of rules each entity is following. Therefore, we ask that the effective date and the compliance date be as near in time as possible and practicable and that all applicable providers or entities be subject to the new rule.

8. The Civitas Community is deeply engaged on this topic and can be resources in the future.

A number of our members, which are listed below, wish to add their individual support for the items raised in this comment letter.

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 Civitas's CEO, Lisa Bari at lbari@citivasforhealth.org.

Sincerely,

Lisa Bari
CEO
Civitas Networks for Health and Civitas Networks for Health Association.

CIVITAS MEMBERS WHO JOIN THIS COMMENT LETTER

Chesapeake Regional Information System for our Patients ("CRISP")
Connxus, the Central Texas Regional Health Information Exchange
CRISP DC
Healthy Alliance
HealthInfoNet
Indiana Health Information Exchange ("IHIE")
Michigan Health Information Network and Shared Services ("MiHIN")
MyHealth Access
SYNCRONYS
Velatura Health Information Exchange Corporation ("VHIEC")