October 15, 2019

Deepa Avula, M.P.H., Director
The Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
5600 Fishers Lane
Room 17E41
Rockville, MD 20857

Submitted electronically via: http://www.regulations.gov

RE: SAMHSA 4162-20 Confidentiality of Substance Use Disorder Patient Records

OCHIN appreciates the opportunity to comment on the Confidentiality of Substance Use Disorder Patient Records and provide our recommendations on the proposed changes to re-disclosure, consent, and research.

OCHIN is a 501(c)(3) not-for-profit community-based health information technology (HIT) collaborative. We are the largest Health Resources and Services Administration (HRSA) Health Center Controlled Network (HCCN) in the country, supporting 96 health centers in our network. We also deliver best-in-class electronic health record (EHR) technology to 112 organizations on our hosted Epic platform. We operate two national broadband consortia, the Oregon Health Network and California Telehealth Network, as well as the California Telehealth Resource Center. OCHIN has exchanged over 100 million patient records with over 2,000 unique external organizations for 2.7 million patients since 2010. Interoperability is pivotal to the success of our work, ensuring our providers have complete patient records to ensure they can deliver safe, coordinated care.

OCHIN’s General Comments:

OCHIN appreciates the opportunity to comment, focusing on a few overarching issues: re-disclosure, consent, and research. We applaud SAMHSA for their continuing efforts to reform the Confidentiality of Substance Use Disorder Patient Records Rule to improve care coordination for patients and providers on the front lines of the substance abuse crisis impacting the nation.

Uncertainty around the Part 2 rules creates barriers that prevent patients and providers from realizing the benefits that may be obtained from having access to electronic health record (EHR) systems. We appreciate and support SAMHSA’s efforts to make it easier to comply with the consent requirement while protecting patient privacy and improving patient safety. On behalf of the 5.1 million patients and 10,000 community health providers we serve, we believe removing hurdles to sharing substance use disorder (SUD) treatment data with other providers does not harm patient privacy but allowing these barriers to remain harms patient health.

OCHIN’s Comments:
Re-Disclosure and Consent

OCHIN applauds SAMHSA’s proposal to allow patients to consent to the disclosure of their information to non-provider entities without having to name a specific individual receiving information on behalf of a given entity. To further this effort, we want to provide the following suggestions:
Use a general designation to closer align 42 CFR Part 2 with HIPAA:

- In the context of an entity facilitating the exchange of health information, OCHIN disagrees with SAMHSA’s proposal to continue limiting a patient’s ability to use a general designation in the “to whom” section of the consent to those individuals or entities with a treating provider relationship.
  - Under the proposed 42 CFR 2.31(a)(4)(i), OCHIN is supportive of SAMHSA’s proposal to allow patients to name non-provider entities in a consent as the recipients of their SUD information. However, this change does not help networks whose patients do not remain static after signing a consent. Compelling patients to sign a new consent whenever a patient moves around within the same network is overly burdensome, as it would require patients with SUD information in the system to sign a new consent form every time they see or are transferred to a new network provider. Therefore, under the proposed 42 CFR 2.31(a)(4)(ii)(B), it is critical to have the ability to use a general designation that includes non-treating providers to describe the potential recipients of the Part 2 information, simply as providers within the network. This becomes even more critical with advancements in interoperability.
  - SAMHSA’s proposal to limit a patient’s ability to use a general designation in the “to whom” section of the consent needlessly exceeds the requirements under the Health Insurance Portability and Accountability Act (HIPAA). Under 45 CFR 164.508(c)(1)(ii), HIPAA permits patients to designate a class of persons on a consent that is authorized to receive protected health information without the “treating provider” limitation.
  - For nearly 20 years, the Department of Health and Human Services has understood and emphasized the importance of the HIPAA general designation option to ensure that individuals are not compelled to sign multiple authorizations for the same purpose.1 SAMHSA’s proposal to limit a patient’s ability to use a general designation continues a longstanding problem of Part 2 requirements that exceed the requirements of HIPAA. OCHIN believes this limitation will continue to limit the ability of patients to control their SUD information and increase provider and patient confusion due to inconsistency between Part 2 and HIPAA. The results of this confusion are both an increase in administrative costs and avoidable harm to patients when pertinent medical information has not been shared.

Extend the logic of the PDMP extension to a general designation:

- OCHIN is aligned with SAMHSA’s reasoning for allowing opioid treatment providers (OTPs) as well as non-OTPs to enroll in Prescription Drug Monitoring Programs (PDMPs) and submit SUD dispensing and prescribing data. As stated by SAMHSA, the inclusion of SUD dispensing and prescribing data in PDMPs will help to ensure patient safety and prevent duplicative treatment plans and medications or prevent drug interactions that could place a patient receiving SUD treatment at risk.
- The reasoning presented by SAMHSA related to the PDMP issue should equally extend to a network’s use of a general designation on patient consent forms. SAMHSA should allow patients to use a broad consent to control how their SUD information is disclosed and used within a network—especially if such disclosure and use may reduce risks within their care. SAMHSA’s current proposal takes power away from SUD patients who would benefit from the care coordination opportunities presented by an expansive network of providers. By not permitting

---

1 65 F.R. 82660 (December 28, 2000).
patients the opportunity to consent generally to the use of their SUD information within a network, such information will continue to remain siloed, putting SUD patients at risk.

**OCHIN’s suggestion for a general designation:**

- Instead of a broad prohibition on the inclusion of providers without a current patient relationship but a possible or likely future patient relationship, SAMHSA should instead allow a general designation by extension of the PDMP logic expressed above to include an entity that has a written contract that requires the entity to comply with Part 2. This concept is similar to SAMHSA’s recent changes to Part 2 that allow a Lawful Holder to disclose patient identifying information for payment and/or health care operations activities to contractors, subcontractors, or legal representatives under 42 CFR 2.33(b) and (c). Based on the text of 42 CFR 2.33(c), SAMHSA clearly believes that the contractual obligations on these non-treating provider entities constitute appropriate protection against improper uses or disclosures of SUD information.

- Consequently, OCHIN requests that SAMHSA make the following underlined revision to the proposed 42 CFR 2.31(a)(4)(ii)(B):
  - A general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed or who has in place a written contract or comparable legal instrument with the individual or entity that requires the participant(s) to be fully bound by the provisions of Part 2 upon receipt of patient identifying information. When using a general designation, a statement must be included on the consent form that the patient (or other individual authorized to sign in lieu of the patient), confirms their understanding that, upon their request and consistent with this part, they must be provided a list of entities to which their information has been disclosed pursuant to the general designation (see §2.13(d)).

**Research**

- OCHIN was pleased to see the proposal to allow disclosures for research to non-HIPAA covered entities provided that any such data will be disclosed in accordance with the HIPAA Privacy Rule. This will allow public health agencies and others that are neither HIPAA covered entities or business associates to obtain Part 2 data to better research the impact of the SUD challenges, including the current opioid epidemic on their population.

We thank you for your time and consideration of our comments on the *Confidentiality of Substance Use Disorder Patient Records* Proposed Rule. Please contact Jennifer Stoll at stollj@ochin.org should you have any questions.

Sincerely,

Jennifer Stoll
EVP, Government Relations and Public Affairs