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January 27, 2023

U.S. Department of Health and Human Services
Office for Civil Rights
Substance Abuse and Mental Health Services Administration
Attention: SUD Patient Records
Hubert H. Humphrey Building, Room
509F, 200 Independence Avenue, SW
Washington, DC 20201

Re: Confidentiality of Substance Use Disorder (SUD) Patient Records

Dear Secretary Becerra and Assistant Secretary Delphin-Rittman:

The Association of American Medical Colleges ("the AAMC" or "Association") welcomes this opportunity to comment on the Department of Health and Human Services (HHS) Notice of Proposed Rulemaking entitled "Confidentiality of Substance Use Disorder Patient Records," 87 *Fed. Reg.* 74216 (December 2, 2022), which proposes changes to the regulations to implement changes from the Coronavirus Aid, Relief and Economic Security (CARES) Act that will better align Part 2 requirements with HIPAA rules. This will facilitate the exchange of information and enable provision of high-quality care for individuals in treatment for substance use disorder (SUD) care while maintaining privacy.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members comprise all 157 accredited U.S. medical schools; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and nearly 80 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 191,000 full-time faculty members, 95,000 medical students, 149,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

The AAMC commends the Department's efforts to modernize the SUD regulations, while also retaining important privacy protections. This issue is of key importance to AAMC members as they care for many patients with SUDs and participate in new delivery models, such as accountable care organizations (ACOs) and episode payment models, that seek to promote high-quality, efficient, and collaborative care. Individuals with SUDs can benefit most from these high-quality coordinated care models if providers are able to access their patients' records that contain all information that is relevant to their treatment, which is consistent with HIPAA. In this

rule, HHS makes welcome changes that will enable better coordination and improve quality of care for individuals with SUDs.

More specific comments in response to this rule are included below.

Uses and Disclosures with Patient Consent

Prior to the CARES act, Part 2 records could only be disclosed with the patient's specific written consent for each disclosure, with limited exceptions. As required in the CARES Act, HHS proposes to replace the current Part 2 consent requirements with a single general consent that would allow a covered entity, business associate, or Part 2 program that receives a Part 2 record pursuant to a consent for treatment, payment, and health care operations (TPO) purposes to use and disclose the Part 2 record for any purpose permitted under the HIPAA Privacy Rule. In addition, HHS proposes to permit a lawful holder that is not a HIPAA-covered entity, business associate, or Part 2 program to redisclose Part 2 records for payment and health care operations to its contractors, subcontractors, or legal representatives as needed to carry out the activities in the consent. A lawful holder, however, would not be permitted to redisclose Part 2 records it receives for treatment purposes before obtaining an additional written consent from the patient. HHS proposes that the Part 2 consent requirements would largely follow the content requirements under HIPAA for a written authorization.

The AAMC strongly supports replacing the current multiple consent requirements with a single general consent. Our members have put considerable effort into ensuring that patient information receives the necessary privacy protections, but the requirement to obtain multiple consents from the patient has been challenging and creates barriers to integrated coordinated approaches to care. Currently, the Part 2 protected information must be segregated from the rest of a patient's medical record and generally may only be made available with patient consent, even when a Part 2 program determines it would be beneficial to the patient to share medical records with a non-Part 2 program in the same practice or health system. Optimal care requires access to a patient's entire treatment history and current medications. Requirements for obtaining specific consent for each use and disclosure makes it difficult to coordinate care and develop comprehensive transition plans.

Even when patients consent, the consent and disclosure process delays sharing essential information. In situations in which a patient has not given consent, the patient may not receive appropriate care. For example, a physician who is unaware of a patient's opioid use disorder history may prescribe opioids to someone in SUD recovery, potentially contributing to relapse. This expanded ability to use and disclose Part 2 records will improve communications and care coordination between providers and with other parts of the health care system. It will enhance the ability of payers to share SUD treatment claims information with alternative payment model providers for population health management and thereby enhance the ability to treat the whole patient. While we believe that the change regarding consent is a positive step in the right direction, in the future we recommend aligning consent requirements with HIPAA, which allows TPA disclosures without consent. We recognize that aligning with HIPAA regarding consents would require a change to the statute.

We urge HHS to ensure that the consent requirements are straightforward, and that providers and patients are not subject to additional administrative processes. The consent process should be part of the existing HIPAA compliance processes, preferably incorporated into the same documents related to acknowledgement of HIPAA practices.

SUD Counseling Notes

The Department solicits comments on whether to propose special protection for SUD counseling notes to "add a layer of regulatory protection that equates to the protection granted to psychotherapy notes in the Privacy Rule" by requiring a separate written consent for their disclosure. We support not disclosing SUD counseling session notes without a separate written authorization or consent. These notes, which are maintained primarily for use by the originator of the notes, should have heightened protections and accountability. This policy would be consistent with the approach that limits the individual's right of access to psychotherapy notes under HIPAA. However, we believe it is still important for the Part 2 treatment program to be allowed to use or disclose these SUD counseling notes for its own training programs in which students, trainees, or practitioners in SUD treatment learn under supervision to practice and improve their counseling skills and support their use and disclosure in this context. We recommend HHS explore in partnership with stakeholders, how these SUD counseling session notes would be best protected while minimizing data segmentation challenges. To minimize administrative burden, we encourage the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office of Civil Rights (OCR) to issue guidance on how these counseling notes could be segregated.

Right to Revoke Consent

As proposed, the patient would have a right to revoke consent in writing or orally. To fully accomplish the aims of the right to revoke consent, the Department states it expects that Part 2 programs would need to ensure that any ongoing or automatic disclosure mechanisms are halted upon receipt of a request for revocation. The proposed rule clarifies that once a Part 2 program discloses a record for TPO, a revocation would only be effective to prevent additional disclosures to a covered entity, business associate, and Part 2 program recipients of Part 2 records, because the CARES Act redisclosure permission for those entities limits the ability to "pull back" Part 2 information from those entities once it is disclosed. It would not prevent a recipient Part 2 program, covered entity, or business associate from using the record for TPO or redisclosing the record as permitted by the Privacy Rule.

We support this approach to revocation. While a patient's ability to revoke consent is an important privacy protection, there would be significant administrative issues if the revocation were retroactive. In addition, the Part 2 treatment entity should receive the notification from the patient about revocation and should maintain the responsibility for managing the revocation and seeing that it is not transmitted to another entity prospectively. We recommend OCR and SAMHSA provide guidance on the best way to flag a revocation within electronic health records and identify technology that can enable this to occur.

Use and Disclosure of Part 2 Records in Proceedings Against the Patient

As required by the CARES act, HHS proposes to expand the prohibitions on the use of Part 2 records in civil, criminal, administrative, or legislative proceedings against the patient absent written patient consent or a court order to expressly include disclosures of Part 2 records. We support this prohibition. Even if sharing of information is made easier, the benefits would be limited without strong protections for patient privacy. If patients are concerned that SUD records will be used against them by law enforcement, they may choose not to seek necessary care.

Requirements for Intermediaries and Accounting of Disclosures

Part 2 currently allows a patient to request a list of disclosures made by an intermediary within the past two years. HHS proposes to retain this right but increase the period to three years consistent with the new right to an accounting. It also proposes to add a definition of the term "intermediary" to mean a person who has received records under a general designation in a written patient consent to be disclosed to one or more of its member participants who has a treating provider relationship with the patient. HHS states that this definition is intended to clarify that health information exchanges (HIEs), research institutions, accountable care organizations and care management organizations would be intermediaries and subject to the requirement to provide patients with a list of disclosures made to member or participant treating providers.

Except for disclosures made by intermediaries, the existing Part regulation does not include a right for patients to obtain an accounting of disclosures of Part 2 records. The CARES Act expanded the right to an accounting of disclosures for treatment, payment or health care operations purposes to disclosures of Part 2 records made with written consent. Therefore, HHS proposes to add a new right to receive an accounting of disclosures of Part 2 records made with written consent for up to three years. These proposed changes would be contingent on promulgation of the HITECH Act modifications to the accounting of disclosures standard in the privacy rule.

HHS asks whether the requirement for intermediaries to provide a list of disclosures on request should be retained. We are concerned that the list of disclosures requirement is costly and administratively burdensome and as a result practitioners may be uncomfortable attempting to use the general consent**.** In addition, there is a concern about workforce safety if full names of individuals in the workforce (e.g. nurses medical assistants, front desk staff and others) are disclosed, particularly as violence in healthcare settings is on the rise. On balance, since the individual has elected to consent to use and disclosure in the first instance and that election is fully informed and voluntary, accounting for the disclosures made pursuant to that consent should not be necessary. At a minimum, we urge the Department not to require an accounting of disclosures until the HIPAA accounting of disclosure requirement is implemented and evaluated.

Intermediaries and Consent

HHS retains the requirement that if the recipient entity under a written consent is an intermediary, its name must be included in the written consent and either (1) the name(s) of the member participants of the intermediary; or (2) a general designation of a participant(s) or class

of participants, which must be limited to a participant(s) who has a treating provider relationship with the patient. We are concerned that the requirement to specifically identify the intermediaries in the consent is overly broad given the proposed definition of "intermediary," which includes entities with widely different activities and purposes. There could be negative ramifications to requiring a separate consent to share information with ACOs and care management organizations. A patient could be assigned to an ACO retrospectively, making it difficult to predict whether consent is needed for a specific ACO. If the driving concern is sharing information with HIEs, we recommend that consents related to HIEs be specifically addressed separate and apart from general consent for treatment, payment, and operational purposes.

Technical Assistance on Part 2 Rule

We urge HHS, OCR and SAMHSA to offer technical assistance to providers, payers, consumers, and other stakeholders as they work to understand and implement the provisions in the rule. This could include establishing learning collaboratives, sharing best practices, holding webinars, providing templates or others examples of policies, and issuing sub-regulatory guidance.

Conclusion

The AAMC appreciates your consideration of the above comments. Should you have any questions, please contact Gayle Lee at galee@aamc.org.

Sincerely,

Jonathan Jaffery, MD, MS, MMM
Chief Health Care Officer

cc: David Skorton, MD, AAMC President and CEO