April 30, 2021

Robinsue Frohboese, JD, PhD
Acting Director and Principal Deputy, Office for Civil Rights (OCR)
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

RE: Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement NPRM, RIN 0945-AA00

Dear Dr. Frohboese:

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 6,600 physicians and associated health professionals who specialize in the prevention and treatment of addiction, thank you for the opportunity to provide comments on the proposed modifications to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to support, and remove barriers to, coordinated care and individual engagement (Proposed Rule). ASAM members have dedicated their careers to treating patients with substance use disorder (SUD) and they strive to provide high quality care that respects patients' privacy and safeguards their sensitive health information. Accordingly, ASAM has supported recent regulatory and legislative changes to align the federal confidentiality protections for SUD patient records known as 42 CFR Part 2 (Part 2) with HIPAA for the purposes of health care treatment, payment, and operations (TPO) while leaving in place certain, critical Part 2 prohibitions on disclosure of records outside the health care system.

This Proposed Rule would modify the Privacy Rule to increase permissible disclosures of protected health information (PHI), *i.e.*, individually identifiable health information maintained or transmitted by or on behalf of HIPAA-covered entities, in an effort to improve care coordination and case management. Importantly, the Proposed Rule would amend the definition of health care operations to clarify the scope of permitted uses and disclosures

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for individual-level care coordination and case management that constitute health care operations. The Proposed Rule also purports to clarify the scope of covered entities' abilities to disclose PHI to social services agencies, community-based organizations, home- and community-based service (HCBS) providers, and other similar third parties that provide health-related services, to facilitate coordination of care and case management for individuals.

Given the recent statutory changes that partially align Part 2 with HIPAA,[1] ASAM has several concerns with this Proposed Rule, as the changes it envisions could allow an individual's SUD-related PHI to be used or disclosed in ways that threaten the confidentiality of such sensitive information. These concerns are detailed below.

Clarifying the Scope of Covered Entities' Abilities To Disclose PHI to Certain Third Parties for Individual-Level Care Coordination and Case Management That Constitutes Treatment or Health Care Operations (45 CFR 164.506)

In the Proposed Rule, the Department asserts that the Privacy Rule contemplates disclosures of PHI to third party organizations *without authorization* for care coordination and case management. HHS proposes to expressly permit covered entities to disclose PHI to social services agencies, community-based organizations, HCBS providers, and other similar third parties that provide health-related services to specific individuals for individual-level care coordination and case management, either as a treatment activity of a covered health care provider or as a health care operations activity of a covered health care provider or health plan. With the recent changes that partially align Part 2 with HIPAA, this PHI could include sensitive SUD-related records if the patient has consented to sharing their records for TPO.

The Proposed Rule states that, under this provision, a health plan or a covered health care provider could only disclose PHI without authorization to a third party that provides health-related services to individuals; however, the third party does not have to be a health care provider. Instead, the third party may be providing health-related social services or other supportive services—*e.g.*, food or sheltered housing needed to address health risks. The Department's understanding is that, in general, the third-party entities receiving PHI under this proposed permission would not be covered entities and thus, the PHI disclosed to them would no longer be protected by the HIPAA Rules. Consequently, an individual's sensitive SUD-related records, were they disclosed under this permission, would no longer be protected.

ASAM strongly opposes an express permission for HIPAA-covered entities to disclose an individual's PHI to non-covered entities without the patient's consent.

The Department acknowledges that some stakeholders have previously expressed concerns about expressly permitting such disclosures without individuals' authorization or consent, and notes that it proposes to limit the scope of this permission to disclosures by covered entities for care coordination and case management for individuals rather than population-based activities. The Department believes that the limitation to individual-level activities will ensure that the disclosures made under this permission would be akin to disclosures for treatment, which individuals expect to occur without their needing to provide an authorization or consent. **ASAM**

disagrees, as disclosures for treatment are made to treating providers, who are themselves HIPAA-covered entities, and the patient's PHI remains protected by the HIPAA Rules. In the express permission contemplated by the Proposed Rule, the disclosures would result in non-covered entities accessing and using a patient's sensitive SUD-related records, which would no longer be protected by HIPAA Rules.

The Department further asserts that the existing Privacy Rule right to request restrictions on disclosures for TPO purposes under 45 CFR 164.522(a) remains available for individuals to request more limited disclosures. However, exercising this right requires an individual to know and understand the right available to them and proactively request restrictions on disclosures of their PHI. ASAM has serious concerns that the patient population this proposal intends to benefit (e.g., people who are experiencing homelessness) generally do not know or understand their ability to request such a restriction.[2]

Therefore, **ASAM strongly urges the Department not to implement this aspect of the Proposed Rule. A patient's consent should be required before their PHI is disclosed, for any reason, to a non-HIPAA-covered entity, and thereby removed from the protection of HIPAA Rules.**

Alternatively, the Department asks whether to limit the proposed express permission to disclose PHI to circumstances in which a particular service provided by a third party is specifically identified in an individual's care plan and/or for which a social need has been identified via a screening assessment. The Department further asks whether it should require, as a condition of the disclosure, that the parties put in place an agreement that describes and/or limits the uses and further disclosures allowed by the third-party recipients. Should the Department move forward with an express permission to disclose PHI to third parties, ASAM believes these safeguards should be established. That is, the permission should be limited to circumstances in which a particular service is specifically identified in an individual's care plan and/or for which a social need has been identified via a screening assessment. Further, it should require as a condition of the disclosure, that the parties put in place an agreement that describes and/or limits the uses and further disclosures allowed by the third-party recipients. The parties should be required to narrowly define the PHI being transmitted, the purpose of the disclosure, and the duration of access, as well as to provide notification in the event of a data breach. Essentially, the Department should require an agreement similar to a Business Associate Agreement to be signed to protect the individual's PHI from improper access, use and disclosure.

Encouraging Disclosures of PHI When Needed to Help Individuals Experiencing Substance Use Disorder (Including Opioid Use Disorder), Serious Mental Illness, and in Emergency Circumstances (45 CFR 164.502 and 164.510-514)

The Proposed Rule also contemplates changes to the criteria for when PHI may be shared without consent in emergency circumstances, such as when an individual is incapacitated due to a drug overdose. HHS proposes to amend the Privacy Rule:

- to replace "the exercise of professional judgment" standard with a standard permitting certain disclosures based on a "good faith belief" about an individual's best interests; and

- to replace the provision that currently permits a covered entity to use or disclose an individual's PHI based on a "serious and imminent threat" with a "serious and reasonably foreseeable threat" standard.

ASAM does not believe these changes are necessary to facilitate communication between a health care professional and a patient's family members or friends involved in the patient's care. The HIPAA Privacy Rule already allows often routine—and sometimes critical—communications between a health care professional and people involved in a patient's care.[3,4] Further, there is no record of OCR or the Department of Justice ever pursuing civil or criminal HIPAA enforcement against covered entities sharing information with family or caregivers to facilitate treatment or payment. Given these facts, it is unnecessary to modify the Privacy Rule as proposed, and the changes may have unintended and unforeseen negative consequences for patients.

In particular, the proposed change from "serious and imminent threat" to "serious and reasonably foreseeable threat" may disproportionately impact Black, Hispanic/Latinx, Asian, Pacific Islander, Native American, and other racially oppressed and disenfranchised people (hereinafter collectively referred to as Black, Indigenous, People of Color (BIPOC)). Every day, addiction medicine professionals confront the tragic consequences of racial injustice among the patients and communities we serve — from the disproportionate incarceration of BIPOC with the disease of addiction, to treatment barriers for many BIPOC, to rising overdose deaths and ongoing discrimination. Health care professionals are not free from conscious or unconscious bias, which can lead to discrimination and inequitable treatment. Such bias may result in BIPOC patients disproportionately being identified as posing a "serious and reasonably foreseeable threat" simply based on their race or ethnicity. The proposed expansion of the threat standard could result in BIPOC patient populations being subjected to additional encounters with law enforcement, suffering additional losses of medical privacy compared to their peers, and becoming increasingly wary of seeking out needed care—all of which would exacerbate our nation's existing health inequities.

The Department asks stakeholders if the rule should be further revised to permit a covered entity to disclose the PHI of an individual who has decision making capacity to the individual's family member, friend, or other person involved in care, in a manner *inconsistent* with the individual's known privacy preferences, based on the covered entity's good faith belief that the use or disclosure is in the individual's best interests, in any situations outside of an emergency circumstance. The Department goes on to ask: Are there examples in which the totality of the facts and circumstances should or would outweigh an individual's preferences, but do not rise to the level of posing a serious and reasonably foreseeable threat? Are there examples related to individuals who have regained capacity after having been formerly incapacitated, such as where an individual recovering from an opioid overdose leaves the hospital against medical advice or leaves a residential treatment program?

ASAM's answer is emphatic: the rule should not be further revised to permit a covered entity to disclose the PHI of an individual with decision-making capacity against the individual's wishes or without their consent unless there is a serious and imminent threat. It is a long-established

legal principle that capacitated patients have the right to exercise their autonomous choice, even when their providers believe, in good faith, that the patient's choice is not in the patient's best interest. Capacitated patients have the right to refuse even life-saving treatment—why would a decision about PHI disclosure be afforded less protection? People with SUD should be afforded the same rights to privacy as other patients and their preferences should be similarly respected. Even if a provider is acting on a good faith belief that a disclosure is in the patient's best interest, it is simply not their choice to make. The right to self-determination in health care decisions and disclosures is fundamental in the United States—beneficent motivations by providers have never been sufficient to overcome contemporaneous patient objections except in very narrow circumstances of incapacity and imminent threats.[5] Further, good faith may be misplaced and decisions about patients with SUD are especially prone to bias. Providers rarely understand the scope or prevalence of the stigma and discrimination patients continue to face and potential negative consequences for the patient of such a disclosure – consequences that adversely affect the patient's employment, housing, health care, child custody, or general well-being.[6] Giving providers the authority to override the patient's privacy preferences, even in "good faith," is not only irresponsible and unethical, but it directly conflicts with well-established, fundamental patient rights.

Finally, the Department asks if there are potential unintended consequences related to granting extra deference to a covered health care provider based on specialized risk assessment training, expertise, or experience when determining that a serious threat exists or that serious harm is reasonably foreseeable, and if there are unintended consequences related to specifying mental and behavioral health professionals as examples of such providers. ASAM believes it would not be advisable to grant extra deference to or require mental or behavioral health professionals to evaluate a patient to determine if a serious harm is reasonably foreseeable, as these providers may not always be available when needed.

Thank you again for the opportunity to provide comments on this Proposed Rule, which would have serious implications for the privacy and confidentiality of patients with SUD. Please contact Susan Awad, Director, Public Policy and Regulatory Affairs at sawad@asam.org should you have any questions related to our comments. ASAM looks forward to working with the Department to further refine the rules governing the confidentiality of patients' SUD-related treatment records to facilitate access to coordinated care while maintaining critical privacy protections.

Sincerely,

Paul Earley, MD, DFASAM
President, American Society of Addiction Medicine

[1] Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No 116-136, 134 Stat 281 (27 March 2020) (CARES Act).

[2] Marie C. Pollio, The Inadequacy of HIPAA's Privacy Rule: The Plain Language Notice of Privacy Practices and Patient Understanding, 60 N.Y.U. ANN. Surv. AM. L. 579 (2004); Charlotte A. Tschider, The Consent Myth: Improving Choice for Patients of the Future, 96 WASH. U. L. REV. 1505 (2019). Available at: https://openscholarship.wustl.edu/law_lawreview/vol96/iss6/12

[3] 45 CFR § 164.510(b). *See also HIPAA Privacy Rule and Sharing Information Related to Mental Health*, available at https://www.hhs.gov/sites/default/files/hipaa-privacy-rule-and-sharing-info-related-to-mental-health.pdf.

[4] *Information Related to Mental and Behavioral Health*, *including Opioid Overdose*, available at https://www.hhs.gov/hipaa/for-professionals/special-topics/mental-health/index.html.

[5] Dineen, Kelly K. RN, JD, PhD. It is Not the Patient, It is the System, Journal of Addiction Medicine: January 20, 2021 - Volume Publish Ahead of Print - Issue - doi: 10.1097/ADM.0000000000000800

[6] Tsai AC, Kiang MV, Barnett ML, et al. Stigma as a fundamental hindrance to the United States opioid overdose crisis response. *PLoS Med*. 2019;16(11):e1002969. Published 2019 Nov 26. doi:10.1371/journal.pmed.1002969