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Via electronic submission (www.regulations.gov)

October 25, 2019

Deepa Avula, MPH
Director, Office of Finance Resources
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
5600 Fishers Lane, Room 17E41
Rockville, MD 20857
Attention: SAMHSA 4162-20

Re: Proposed Rule: Confidentiality of Substance Use Disorder Patient Records Regulations (SAMHSA 4162-20)

Dear Director Avula:

The Association of American Medical Colleges ("the AAMC" or "Association") welcomes this opportunity to comment on the Substance Abuse and Mental Health Services Administration (SAMHSA) proposed changes to the Confidentiality of Substance Use Disorder Patient Records regulations to better facilitate the exchange of information for individuals in treatment for substance use disorder (SUD) care. (84 FR 44568). The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 154 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Together, these institutions and individuals are the American academic medicine community.

The AAMC commends SAMHSA'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. In this rule, SAMHSA makes welcome clarifications regarding the application of the current regulations that will enable better coordination and improve quality of care for individuals with SUDs. These clarifications make the regulations more understandable and less burdensome.

While we support many of the changes and clarifications proposed in this rule, we believe that there are still more changes that need to be made to eliminate barriers to care. We recommend better alignment of the Part 2 requirements with the Health Insurance Portability and Accountability Act (HIPAA) protections to maintain privacy while enabling the provision of high-quality care. We recognize that Congress will need to take action to improve alignment with HIPAA and urge SAMHSA to support efforts to change the law to allow sharing of this essential information in the medical record for treatment purposes.

Our members have put considerable effort into ensuring that patient information receives the necessary privacy protections, but the implementation of Part 2 continues to be a barrier to providing effective care for patients with SUDs. 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 would like 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 can make it difficult to coordinate care and develop comprehensive transition plans. Even when patients consent, the consent and disclosure process delays sharing essential information. If a patient does not consent to disclosure of his/her medical requirements and does not convey important information about his/her treatment to the provider, the patient may be at risk for unsafe 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.

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

Applicability of Part 2 Rules to Non-Part 2 Providers

There has been confusion about whether all records of non-Part 2 entities or providers (for example, primary care providers) are subject to Part 2 restrictions when the records include information about a patient's SUD treatment and status. SAMHSA proposes to clarify that the records of non-Part 2 entities are not covered by Part 2 restrictions simply because they describe information about a patient's SUD treatment and status. AAMC strongly supports this clarification. It is important for providers to have assurance that this information in a patient's medical record does not subject them to Part 2 restrictions. This will ensure that individuals with SUDs receive coordinated care from Part 2 providers and other types of providers and entities.

This clarification will be particularly helpful to academic medical centers (AMCs) that offer innovative approaches to care for patients with substance abuse disorders. For example, some AMCs offer centers that provide comprehensive, coordinated and multi-disciplinary approaches to care for drug-dependent mothers and their drug-affected babies. In the past, the obstetrics and gynecology physicians (OB GYNs) who deliver the babies and the pediatricians who treat them may have had challenges accessing information about the mother's substance abuse disorders even though they are in the same health system due to the Part 2 restrictions. When they obtain the information, these physicians have been uncertain of whether their medical records will be subject to the Part 2 restrictions if they document information about the mother's SUD in the record. Yet, it is essential for the pediatricians to know if the baby's mother has a substance

abuse disorder and to document that information in their medical records so that they can ensure appropriate follow-up treatment for the baby. This clarification assures them that they can document this information in the record without being subject to Part 2 restrictions.

In addition, this clarification will also be helpful in instances when academic medical centers treat patients with substance use disorders that also have significant adult illnesses, such as cardiovascular disease. There are often transfers between units in the hospital during the hospital stay, and this will enable better coordination of care for these patients.

SAMHSA also proposes to create a new subsection that would specifically state that a non-Part 2 treating provider may record information about a SUD and its treatment that identifies a patient, as long as any Part 2 records are segregated from the non-Part 2 provider records. SAMHSA also notes that segregating those records could be straightforward when the Part 2 records are paper records or email attachments, and that segregating electronic records could be accomplished by use of a Data Segmentation for Privacy (DS4P) compliant EHR platform.

While we are supportive of this clarification, we would like to point out that segregating records can be challenging. For providers using EHRs, there are difficulties with segmenting Part 2 protected data from other health information. There are currently no federal requirements for EHRs to include Data Segmentation for Privacy (DS4P) standards. It is also unclear if it is feasible to include this information/standards in EHRs at this time. ONC and SAMHSA have developed the DS4P standard and the Consent2Share software application to manage patient consent preferences. However, the Health Information Technology Standards Committee advising ONC called into question the maturity of the DS4P standard and has suggested that additional testing and refinements are needed. In addition, health IT (HIT) developers and vendors need time to buildout full data segmentation capabilities, and to implement and test the enhanced technology in the clinical setting.

Consent Requirements

Existing rules permit patients to consent to the sharing of their Part 2 protected information. The rules describe the elements that must be included in a written consent for sharing such information. The written consent requires that the information be disclosed to a named individual. SAMHSA proposes to amend its rules to permit disclosures to an entity as well as to an individual. The AAMC supports this change as it will enable individuals to seek benefits from governmental and non-governmental entities, such as Social Security benefits and sober living programs, which contribute to the overall health of individuals.

The AAMC recommends that SAMHSA go one step further and allow patients the choice to provide global consent in advance for all their current and future treatment providers to receive their full medical records. This would result in better care coordination and avoid delays in care. This approach has been taken by Health Information Exchanges (HIEs) that allow individuals to consent in advance to their information to be routed among current and future participating health care providers.

Definition of Records

In the current regulation, "Records" is defined, in part, to mean "any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient." SAMHSA proposes a conforming amendment to the definition of "records" by adding that "information conveyed orally by a part 2 program to a non-part 2 provider for treatment purposes with the consent of the patient does not become a record subject to this part in the possession of the non-part 2 provider merely because that information is reduced to writing by that non-part 2 provider. The effect of this proposed amendment would be to incorporate a limited exception to the definition of records.

We appreciate this clarification and request that SAMHSA revise the language to remove the requirement that the information be conveyed "orally" in order to meet the exception. Often, information about patients may be conveyed to a provider through electronic means, such as through a Health Information Exchange. If this information is received through electronic means, it should not become a record subject to Part 2 if the non-part 2 provider includes it in his/her record.

Disclosures Permitted with Written Consent

Existing Part 2 rules permit a patient to consent to disclosure of their records for payment, and/or health care operations activities. SAMHSA proposes to add 17 examples in the regulatory text of permitted payment and health care operations. SAMHSA states that permitted uses are not intended to include care coordination or case management nor disclosures to contractors, subcontractors, or legal representatives for those purposes. We appreciate the addition of the examples of permitted payment and health care operations but are concerned with the exclusion of disclosures for care management and coordination purposes. The exclusion of care coordination and care management is inconsistent with the Health Insurance Portability and Accountability (HIPAA) Privacy Rule which incorporates these activities in the definition of "health care operations."

These activities contribute to patient safety and disclosure should be allowed as necessary. SAMSHA states that disclosures for care management and care coordination purposes are permitted under other provisions of Part 2. The 2017 update to Part 2 now allows patients to make a "general designation" of an individual or entity to whom information can be disclosed, so long as that person or entity has a "treating provider relationship" with the patient. It is unclear whether care coordinators can be considered to have a treating provider relationship with the patient for purposes of the general designation option. Accountable care organizations (ACOs) may find this challenging, even if care coordinators are considered to have the requisite provider relationship. In many ACO arrangements (both through Medicare and private payers) patients are passively attributed to the ACO and may not recognize the ACO's role in coordinating his or her care.

Disclosures to Prescription Drug Monitoring Programs

SAMHSA points out that 41 states and the District of Columbia have established and require the use of prescription drug monitoring programs (PDMPs). Doctors in 41 states are required to use the PDMP to examine the prescription history of a person before writing a prescription for opioids or controlled substances. Opioid Treatment Programs (OTPs), however, are not permitted under existing rules to submit information about dispensing of controlled substances to those PDMPs. In light of the public health crises presented by the opioid epidemic, SAMHSA proposes to permit OTPs to report SUD medications prescribed or dispensed to the applicable state PDMP with the written consent of the patient.

The AAMC supports this change. With the addition of the OTP data, we expect there will be fewer adverse events or fatal drug interactions that occur. However, we note that the requirement for written consent will still pose some challenges to the inclusion of this important information in the PDMP.

Disclosures to Prevent Multiple Enrollments

Under existing rules, patient records (with consent) may be disclosed to a central registry and to a withdrawal management or maintenance treatment program within 200 miles of a Part 2 program. These disclosures are intended to minimize dual enrollments in treatment programs and to minimize adverse drug events when two different programs are prescribing the same, similar or other drugs that may interact with each other and cause adverse events. Under current rules, a central registry may only disclose such information when asked by a "member program" about a patient's enrollment in another program. SAMHSA proposes to expand the scope of this permitted disclosure so that non-OTP providers with a treating provider relationship may query a central registry to determine if their patient is already receiving opioid treatment. We support this change as it will help to reduce adverse events.

Research Disclosures

Under the current regulations, SAMHSA Part 2 programs are permitted to disclose patient identifying information for research purposes without patient consent if the recipient of that information is a HIPAA covered entity or business associate or subject to the Department of Health and Human Services' (HHS) Federal Policy for the Protection of Human Subjects under 45 CFR part 46 ("Common Rule"), and has obtained and documented authorization from the patient or a waiver or alternation of authorization consistent with the HIPAA Privacy Rule (45 CFR 164.508 or 164.512(i)). SAMHSA has proposed modifying 42 CFR 2.52(a), "Disclosures for the Purpose of Research," to permit disclosures of Part 2 data for research purposes from a HIPAA covered entity or business associate to individuals and organizations that are *not* HIPAA entities or subject to the Common Rule (e.g., state agencies, professional associations) provided this information is disclosed in accordance with HIPAA.

The AAMC appreciates SAMHSA's recognition of the need for more scientific research using SUD-related data, particularly in light of the national opioid epidemic. The AAMC applauds

SAMHSA's efforts to increase access to SUD research while ensuring that rigorous privacy protections for patients and research subjects are in place.

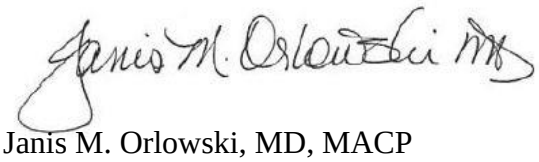
We agree with SAMHSA that more closely aligning the research disclosure requirements in Part 2 (§2.52) with HIPAA and human subject protection requirements under the Common Rule, could help "minimize any conflict or duplication in the requirements for consent to disclosure of records for the purpose of research." (84 Fed. Reg 44578). We also believe that permitting research disclosures to recipients covered under the Food and Drug Administration's (FDA) regulations for human subject protection in clinical investigations (21 CFR part 50) and to members of the workforce of a HIPAA covered entity, also reduces unnecessary barriers to making SUD treatment records more accessible to qualified researchers conducting important ethical research.

The AAMC also encourages SAMHSA to develop FAQs or guidance to ensure that institutions and entities that are not covered entities under HIPAA but who are making disclosures "in accordance with the HIPAA Privacy Rule" understand their obligations and responsibilities. This may include guidance on the accounting and documentation of patient authorization (or waiver/alteration of authorization) and/or the steps to ensure the protection of PHI from improper use.

CONCLUSION

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

Sincerely,



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