



October 25, 2019

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Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attention: SAMHSA – Deeepa Avula
5600 Fishers Lane, Room 17E41
Rockville, MD 20857

Re: Comments on Notice of Proposed Rulemaking regarding
Confidentiality of Substance Use Disorder Patient Records (SAMHSA-4162-
20; RIN 0930-AA32)

Dear Ms. Avula,

On behalf of the American Society of Addiction Medicine (“ASAM”), a national medical specialty society representing more than 6,000 physicians and associated health professionals who specialize in the prevention and treatment of addiction, thank you for the opportunity to provide these comments on proposed modifications to 42 CFR Part 2 (“Part 2”) in the Substance Abuse and Mental Health Services Administration (“SAMHSA”)’s August 26, 2019 notice of proposed rulemaking (84 Fed. Reg. 44568) (the “NPRM”). For decades, ASAM members have dedicated their careers to treating patients with substance use disorder (“SUD”) and strive to provide high quality care that respects patients’ privacy and safeguards their sensitive health information. Accordingly, ASAM continues to support regulatory and legislative changes that would more closely align Part 2 with the Health Insurance Portability and Accountability Act (“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 healthcare system. Thus, I am grateful for this opportunity to provide ASAM’s comments to the NPRM.

Definitions, Applicability, and Prohibition on Re-Disclosure (§2.11, §2.12, and §2.32))

The NPRM acknowledges existing confusion on what is considered unrecorded information and which record-keeping activities of non-Part 2 providers are not governed by Part 2. To facilitate communications and coordination between Part 2 programs and non-Part 2 providers and provide much-needed clarity, the NPRM aims to ensure non-Part 2

providers no longer fear violating Part 2 due to receiving and reading protected SUD patient records. Specifically, SAMHSA proposes to clarify the definition of “records” in §2.11, the applicability provisions in §2.12, and the prohibition on re-disclosures in §2.32 so that treatment records created by non-part 2 providers based on their own patient encounters will not suddenly be covered by Part 2. In other words, so long as non-Part 2 providers segment or hold apart Part 2 records it previously received, non-Part 2 providers would be comfortable that new records they create will not become subject to Part 2.

ASAM supports these proposed clarifications to facilitate care coordination activities by non- Part 2 providers. Further, in order to ensure non-Part 2 providers do not fear inadvertently violating Part 2 due to receiving and reading protected SUD patient records, ASAM also requests additional clarifying language in the proposed revisions to §2.12(d)(2)(ii) as follows:

(ii) Notwithstanding paragraph (2)(i)(C) of this section, a non-part 2 treating provider may record information about a substance use disorder (SUD) and its treatment that identifies a patient. This is permitted and does not constitute a record that has been re-disclosed under part 2, provided that any SUD records received from a part 2 program or other lawful holder are segregated or segmented. The act of recording information about a SUD and its treatment does not ~~by itself~~ render a medical record which is created by a non-part 2 treating provider for clinical purposes, as determined by the non-part 2 provider, including but not limited to, care coordination and case management, subject to the restrictions of this part 2.

Consent Requirements (§2.31)

In the NPRM, SAMHSA proposes changes in §2.31 that would permit a patient to consent to the disclosure of his or her Part 2 treatment records to an entity, without naming a specific person as the recipient for the disclosure. **ASAM supports this change. ASAM further recommends that SAMHSA make additional revisions which would (1) permit generalized consents, authorizing both disclosures and re-disclosures of Part 2 records for TPO purposes among HIPAA “covered entities,” Part 2 programs, and HIPAA “business associates” and (2) permit the use of an “opt out” consent process, where the Part 2 records could be disclosed and re-disclosed for TPO purposes, consistent with HIPAA, unless the patient “opted out.”** Nothing in 42 U.S.C. §290dd-2, itself, appears to impose a re-disclosure prohibition or specify the unique criteria of a valid consent with the specificity that Part 2 currently requires. Therefore, such additional changes would further align Part 2 with HIPAA for TPO purposes and further integrate Part 2 records with other medical records for TPO purposes, which ASAM supports.

Disclosures Permitted With Written Consent (§2.33)

In order to resolve lingering confusion under Part 2 regarding what activities count as "payment and health care operations," SAMHSA proposes that an illustrative list of permissible activities that it considers to be payment and healthcare operations be moved from preamble language to the regulation text. **ASAM supports these changes.** Unfortunately, SAMHSA also reiterates that §2.33(b) is not intended to cover care coordination or case management, and disclosures to contractors, subcontractors, and legal representatives to carry out such purposes are not to be permitted under this particular subsection.

While SAMHSA acknowledges that this policy decision differs from the HIPAA Privacy Rule under which “health care operations” encompasses case management and care coordination activities, SAMHSA

points to, among other provisions, its proposal to revise Part 2's applicability as a way in which the agency can help facilitate coordination of care. As noted above, however, §2.12 can, and should, be further clarified to incorporate care coordination and case management as part of a non-Part 2 provider's clinical purposes in order to achieve SAMHSA's stated goal of facilitating care coordination. Without such clarifications, many non-Part 2 providers may continue to fear violating Part 2 due to receiving and reading protected SUD patient records.

Further, it is important to note that characterizing clarifying language in §2.12 as preserving patient choice, on the one hand, while declining to add care coordination and case management to the list of allowable reasons for disclosure with patient consent in §2.33(b) on the other, is largely a distinction without a difference, save one, in the context of non-Part 2 providers: it puts the burden on non-Part 2 providers to take the additional step of recording SUD information into new records. Since this extra step involves non-Part 2 providers using their discretion, it is difficult to see how this difference either enhances patient autonomy or better facilitates care coordination and case management in comparison to revisions to §2.33(b) that would actually empower patients to give a consent that covers re-disclosures for care coordination and case management. In addition, the logic used by SAMHSA to support revisions to Part 2 applicability could one day be extended to all non-Part 2 lawful holders that may create their own records. For example, health plans create their own records as part of payment processes for Part 2 programs.ⁱ Are those new records governed by Part 2? If not, then those new records could arguably "flow" for any HIPAA permitted purpose, not just for TPO.

Thus, ASAM respectfully requests that SAMHSA better balance patients' privacy protections against the need for non-Part 2 providers to be able to offer appropriate medical services to patients with SUD by adding care coordination and case management to the list of allowable reasons for further disclosure under the terms of the patient's consent for disclosure for health care operations.ⁱⁱ Revising the definition of "health care operations" in this way would not only further align Part 2 with the HIPAA Privacy Rule for TPO purposes,ⁱⁱⁱ but would avoid the "slippery slope" of possibly expanding the proposed Part 2 applicability changes to other non-Part 2 lawful holders and for purposes beyond TPO. Alternatively, SAMHSA could further align Part 2 with HIPAA for TPO purposes by refining the definition of QSOs in Part 2 regulations to include case management and care coordination and better align QSO agreements with the standards for business associate agreements under HIPAA.

Disclosures to Central Registries and PDMPs (§2.34 and §2.36)

SAMHSA's proposed changes to §2.34 and §2.36 would allow non-OTP (opioid treatment program) providers to become eligible to query a central registry, in order to determine whether their patients are already receiving opioid treatment through a member program and prevent multiple enrollments. Additionally, the proposed changes would allow OTPs to enroll in a state prescription drug monitoring program (PDMP) and report data into the PDMP when prescribing or dispensing medications on Schedules II to V, consistent with applicable state law. **Consistent with ASAM's [Public Policy Statement on Prescription Drug Monitoring Programs](#), ASAM supports these changes to help prevent duplicative enrollments in SUD care, duplicative prescriptions for SUD treatment, and adverse drug events related to SUD treatment. ASAM further recommends that (1) PDMP systems notify PDMP users that information related to medications dispensed from OTP's may still be incomplete as a result of patient consent requirements and (2) OTP enrollment in, and reporting of data into, state PDMPs be limited to PDMPs in those states in which applicable state law provides that (a) PDMP data is accessible only**

for clinical treatment and/or evaluation (including consultations by clinicians who are not treating the patient) and for public health purposes by authorized clinicians and researchers, including for ongoing public health analysis that can critically evaluate the impact of any interventions on prescribing practices, and (b) law enforcement officials only be allowed access to PDMP data on a case-by-case basis, through at least a subpoena and within a tightly regulated process.

Undercover Agents and Informants

SAMHSA proposes changes to §2.67 that would allow court-ordered placement of an undercover agent or informant within a Part 2 program to be extended to a total period of 12 months, starting on the date that the undercover agent or informant is placed within the program, and courts would also be authorized to further extend the period of placement through a new court order. **ASAM opposes this change. No provider or patient group is requesting this change. The change does not purport to improve care coordination. There is no evidence presented that the current policy is encumbering ongoing investigations of Part 2 programs.**

Strengthen Patient Protections and Breach Notification

ASAM also encourages SAMHSA to strengthen protections against the use of Part 2 records in criminal, civil, or administrative contexts and to amplify patient protections by incorporating HIPAA requirements for breach into Part 2. Currently, there is no requirement under Part 2 to report or inform if a breach has happened. **ASAM strongly encourages SAMHSA to identify ways, such as these, to increase safeguards and protections against the unauthorized use and disclosure of Part 2 records and personal health information.**

Again, ASAM is grateful for the opportunity to comment on this NPRM. ASAM will continue to advocate for the highest treatment standards and the most compassionate care for patients with SUD. We must ensure our patients can easily access state-of-the-art treatment within our healthcare system, and SAMHSA's efforts in this regard are greatly appreciated. If you have any questions or concerns, please contact Kelly Corredor, ASAM's Vice President of Advocacy and Government Relations, at kcorredor@asam.org or at 301-547-4111.

Thank you,

A handwritten signature in blue ink that reads "Paul H Earley M.D." The signature is written in a cursive, flowing style.

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

ⁱ Weinstein, Scott, et.al. (2019, September 30). SAMHSA Proposed Rule Would Reduce Barriers To Care Coordination [The National Law Review blog post]. Retrieved from

<https://www.natlawreview.com/article/samhsa-proposed-rule-would-reduce-barriers-to-care-coordination>.

ⁱⁱ [Modernizing Privacy Regulations for Addiction Treatment Records H-315.965](#) and [Confidentiality and Privacy Protections Ensuring Care Coordination and the Patient-Physician Relationship H-315.964](#) (Policies of the American Medical Association)

ⁱⁱⁱ [Confidentiality and Privacy Protections Ensuring Care Coordination and the Patient-Physician Relationship H-315.964](#) (Policy of the American Medical Association)