October 25, 2019

BY ELECTRONIC SUBMISSION

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

RE: Comments on Proposed Rule: 42 CFR Part 2, Confidentiality of Substance Use Disorder Patient Records

SAMHSA:

On behalf of state health data organizations that collect and maintain statewide All-Payer Claims Databases (APCDs), the All-Payer Claims Database (APCD) Council submits these comments in response to proposed revisions to 42 CFR Part 2 governing the confidentiality of Substance Use Disorder (SUD) patient records. We commend the Substance Abuse and Mental Health Services Administration's (SAMHSA) thoughtful consideration of the modifications to 42 CFR Part 2 to address concerns that have been raised by state health data agencies and others.

The APCD Council is a learning collaborative of government, private, non-profit, and academic organizations focused on improving the development and deployment of state APCDs. The APCD Council is convened and coordinated by the Institute for Health Policy and Practice (IHPP) at the University of New Hampshire (UNH) and the National Association of Health Data Organizations (NAHDO). Our work includes over 10 years' experience with state APCDs, working across states and other stakeholders to seek innovative solutions to technical and reporting challenges faced by these large-scale claims data initiatives.

APCD Council appreciates the clarification provided in the explanatory text from the notice of proposed rule-making that offers guidance to what has caused restrictions on the release of data that preclude state agencies from receiving critical information about SUD and SUD treatment that is necessary for informed policy discussion. This includes:

- SAMHSA proposes to amend § 2.12 to clearly state in the regulatory text that the recording of information about a SUD and its treatment by a non-part 2 entity does not, by itself, render a medical record subject to the restrictions of 42 CFR part 2, provided that the non-part 2 entity segregates any specific SUD records received from a part 2 program (either directly, or through another lawful holder).
- SAMHSA also proposes amendments to § 2.53 (Audit and Evaluation) together with clarifying guidance, under Section III.J. The

amendments to § 2.53 would help to resolve confusion about permitted types of disclosures to and from federal, state and local governmental agencies and to and from third-party payers, for the purpose of audit and evaluation, among other changes.

- Likewise, in section III.I., Research, SAMHSA proposes to allow research disclosures of part 2 patient data by a HIPAA covered entity to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule, for the purpose of conducting scientific research.

In addition, the clarifications provided in the "B. Applicability" section provides clarity about

- When SAMHSA expanded the reach of the Applicability provision in 2017, the intent was not…to make the records of non-part 2 entities (such as some primary care providers) directly subject to 42 CFR part 2, simply because information about SUD status and treatment might be included in those records.

More specifically, in the explanatory text related to section "§2.52 Research", we commend SAMHSA in its recognition that:

Specifically related to section § 2.52 Research, we are encouraged by the intent to allow for sharing of data for legitimate stakeholders, which would include state health data agencies:

- Since the 2017 Final Rule, SAMHSA has become aware that limiting research disclosures under § 2.52, to only HIPAA-covered entities or institutions subject to the Common Rule, may make it more difficult for some legitimate stakeholders to obtain data from SUD treatment records, for the purpose of conducting scientific research. For example, under the current provisions of § 2.52, the disclosure by a lawful holder of SUD records for the purpose of research to a State agency without a part 2 patient consent may be barred, given that most State agencies are neither HIPAA covered entities nor directly subject to the Common Rule. It is not SAMHSA's intention or policy to make it more burdensome for these sorts of stakeholders to carry out scientific research.

The proposed modifications to §2.52 Research could be strengthened to permit the disclosure to state agencies as expressly addressed in the explanation above by adding to the proposed change that information may be disclosed to state agencies that are authorized by law to collect or receive such information, but that are neither HIPAA covered entities, nor subject to the Common Rule. This could be a change reflected in (ii) or (v), below.

§ 2.52 Research.

- Notwithstanding other provisions of this part, including paragraph (b)(2) of this section, patient identifying information may be disclosed for the purposes of the recipient conducting scientific research if:
- (1) The individual designated as director or managing director, or individual otherwise vested with authority to act as chief executive officer or their designee, of a part 2 program or other lawful holder of part 2 data, makes a determination that the recipient of the patient identifying information is:
- (ii) Subject to the HHS regulations regarding the protection of human subjects (45 CFR part 46), and provides documentation either that the researcher is in compliance with the requirements of the HHS regulations, including the requirements related to informed consent or a waiver of consent (45 CFR 46.111 and 46.116) or that the research qualifies for exemption under the HHS regulations (45 CFR 46.104) or any successor regulations;
- (v) any combination of a HIPAA covered entity or business associate, and/or subject to the HHS regulations regarding the protection of human subjects, and/or subject to the FDA regulations regarding the protection of human subjects, and has met the requirements of paragraph (a)(1)(i), (ii) (iii), and/or (iv) of this section, as applicable.

We also appreciate the recognition in the proposed modifications that state agencies have audit and evaluation responsibilities that necessitate the receipt of Part 2 protected data. The explanatory text that clarifies this is helpful.

- First, some stakeholders have voiced frustration that part 2 programs have been unwilling or unable to disclose patient records that may be needed by federal, state, and local agencies, to better serve and protect patients with SUD. For example, a state Medicaid Agency or state or local health department may need to know about specific types of challenges faced by patients receiving opioid therapy treatment, such as co-occurring medical or psychiatric conditions, or social and economic factors that impede treatment or recovery. An agency may need this kind of information to recommend or mandate improved medical care approaches; to target limited resources more effectively to care for patients; or to adjust specific Medicaid or other program policies or processes related to payment or coverage to facilitate adequate coverage and payment. Government agencies may also wish to know how many patients test positive for a new and harmful illicit drug, and how part 2 programs are actually treating those patients, as an input to agency decisions aimed at improving quality of care. For example, agencies may wish to modify requirements for part 2 programs, educate or provide additional oversight of part 2 providers, and/or update corresponding payment or

coverage policies. Third-party payers covering patients in a part 2 program may have similar objectives for obtaining part 2 information.

- Therefore, a part 2 program or other lawful holder may share non-identifiable information with government agencies (federal, state and local) for many types of activities.
- SAMHSA proposes to clarify that under § 2.53, government agencies and third-party payer entities would be permitted to obtain part 2 records without written patient consent to periodically conduct audits or evaluations for purposes such as identifying agency or health plan actions or policy changes aimed at improving care and outcomes for part 2 patients (e.g., provider education, recommending or requiring improved health care approaches); targeting limited resources more effectively to better care for patients; or adjusting specific Medicaid or other insurance components to facilitate adequate coverage and payment. These agencies and third-party payers are required to abide by the restrictions on disclosure and other relevant confidentiality requirements outlined in § 2.53.
- Second, SAMHSA has received feedback that stakeholders are unclear about whether § 2.53 allows federal, state, and local government agencies and third-party payers to have access to patient information for activities related to reviews of appropriateness of medical care, medical necessity, and utilization of services. As described above, the current regulations allow information to be disclosed to certain federal, state, and local governmental agencies and third party payers for audit or evaluation purposes, as long as they agree to specific restrictions outlined in the regulations to limit disclosure or use of the records and preserve patient confidentiality. While neither the statute nor the regulations define audit or evaluation, these terms should and do include audits or evaluations to review whether patients are receiving appropriate services in the appropriate setting.

We commend SAMHSA on making changes in Section § 2.53 Audit and Evaluation to explicitly address the state needs for information.

§ 2.53 Audit and evaluation.

(c) Activities Included. Audits and evaluations under this section may include, but are not limited to:

(1) Activities periodically undertaken by a federal, state, or local governmental agency, or a third-party payer entity, in order to:

(i) Identify actions the agency or third-party payer entity can make, such as changes to its policies or procedures, to improve care and outcomes across part 2 programs;

(ii) Target limited resources more effectively; or

(iii) Determine the need for adjustments to payment policies for the care of patients with SUD; and

(2) Reviews of appropriateness of medical care, medical necessity, and utilization of services.
(g) Audits and Evaluations Mandated by Statute or Regulation. Patient identifying information may be disclosed to federal, state, or local government agencies, and the contractors, subcontractors, and legal representatives of such agencies, in the course of conducting audits or evaluations mandated by statute or regulation, if those audits or evaluations cannot be carried out using de-identified information.

We appreciate SAMHSA's recognition and response to the concerns brought forward by state agencies related to the perceived restrictions on sharing data resultant from the 42 CFR Part 2 regulation. We also appreciate this opportunity to comment on SAMHSA proposed rule. We would be happy to discuss our comments further, if you would like any clarification.

Sincerely,

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