January 31, 2023

The Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attn: SAMHSA-4162-20
5600 Fishers Lane, Room 13N02B
Rockville, Maryland 20857

To Whom It May Concern:

The APCD Council, a program partnership between the National Association of Health Data Organizations and the Institute for Health Policy and Practice at the University of New Hampshire, is a learning collaborative to support states in their All-Payer Claims Database (APCD) work. The APCD Council commends SAMHSA on its continued work to refine and clarify 42 CFR Part 2: Confidentiality of Substance Use Disorder (SUD) Patient Records. Among the changes proposed, we understand that these proposed rule changes seek to align 42 CFR Part 2 and HIPAA rules for information collection and sharing, making compliance easier for entities that are subject to both sets of rules.

We have some suggestions for strengthening this effort.

State health data organizations (HDOs) play a vital role in state health policy and state health improvement efforts across the United States. These HDOs typically collect a variety of healthcare data through statutory authority. These data can include hospital discharge data, encounter data, enrollment data, and health care claims data. The HDOs then use these data to provide information to fulfill a wide range of needs, including those of public health, and often meet regulatory requirements for analysis.

Given these obligations, having reliable information about the need for substance use disorder treatment is vitally important to these state agencies. SAMHSA recognized this and the ability of states to address these needs under the 42 CFR Part 2 rules released in 2020, noting in the preamble:

> "SAMHSA proposed 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 (pg 43023)."

However, there continues to be confusion within the data submitter community about the ability of health insurance carriers to legally submit data to state HDOs without patient consent. There is an opportunity for SAMHSA to explicitly identify this use as an authorized release of data to state agencies. Alternatively, SAMHSA could provide sub-regulatory guidance for the existing rules with this necessary clarification rather than use the rule-making process.

The APCD Council strongly encourages SAMHSA to issue this guidance as quickly as possible to alleviate the confusion about the ability of states to receive Part 2 data, as this does not require any change to the existing rule (and would not change with the proposed rule changes).

In addition to this clarification about the ability of states to collect Part 2 data, we suggest that SAMHSA consider the following items for further specification to avoid potential confusion in the future:

1. **We request that SAMHSA confirm that the de-identification standard includes Safe Harbor and expert determination.** As public health authorities, many states leverage their ability to receive de-identified data. There is potential confusion in aligning the de-identification provisions: there is a reference to 45 CFR 164.514(b), but the proposed language aligns with subsection (a). Subsection (b) is the accepted de-identification method, not the definition in subsection (a).
2. **We suggest that SAMHSA provide guidance regarding allowed redisclosure related to uses for Treatment, Payment, and Operations (TPO) for state agencies to meet obligations.** State agencies serve important roles as data stewards and disseminators of health data for various purposes, including supporting interagency needs. If HIPAA entities receive SUD for TPO, are they authorized to further redisclose for all purposes permitted under 45 CFR Part 164 or only those permitted under 45 CFR Part 164 related to TPO? If SAMHSA's interpretation is the former, it may authorize state APCD agencies to receive SUD from HIPAA entities, so long as it is permitted under HIPAA.
3. **We suggest that SAMHSA provide clarification to understand better if the limitations in §2.53(f) apply to audits/evaluations conducted under all of §2.53 or only those <u>preceding</u> §2.53(f).** As indicated in the above-cited language from the 2020 rule

preamble, the audit and evaluation parameters in §2.53 are particularly important for state agencies.

4. **We suggest that SAMHSA specify its intended definition of research or researcher in Part 2 to clarify to whom the section applies.** 42 CFR Part 2 and HIPAA reference Research and Researchers. It would be helpful to resolve any differences.

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