October 25, 2019

VIA ELECTRONIC MAIL

Elinore F. McCance-Katz, M.D., Ph.D.
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane, Rockville, MD 20857

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

Dear Assistant Secretary McCance-Katz:

The Health Care Transformation Task Force (HCTTF or Task Force) appreciates the opportunity to comment on the Substance Abuse and Mental Health Services Administration (SAMHSA) proposed rule on the Confidentiality of Substance Use Disorder (SUD) Patient Records (Proposed Rule), which proposes changes to 42 CFR Part 2.

The HCTTF is a leading private sector, multi-stakeholder consortium that supports accelerating the pace of transforming the delivery system into one that better pays for value. Representing a diverse set of organizations from various segments of the industry – including providers, health plans, employers, and consumers – we share a common commitment to transform our respective businesses and clinical models to deliver better health and better care at reduced costs. Integration of behavioral health services and comprehensive care coordination is critical to delivering high-quality, patient-centered care for patients with substance use disorders.

We appreciate that SAMHSA recognizes the significant confusion and misunderstanding surrounding the applicability of Part 2 rules. The Task Force does not take a position on the proposed modifications to Part 2; our diverse membership was not able to reach consensus on this issue. However, Task Force members are concerned that the proposal misses an opportunity to address significant areas of ambiguity regarding the applicability of Part 2. The Proposed Rule does not, for instance, further clarify what "holds itself out" means in the Part 2 program definition. The ambiguity creates undue burden and confusion for patients and non-Part 2 health care stakeholders that provide treatment and/or health care operations services for patients with SUD. In this letter, the Task Force identifies two opportunities for SAMHSA to further mitigate confusion and encourage better care coordination and high-quality care for SUD patients.

I. Identifying a Part 2 Provider

In the Proposed Rule, SAMHSA offers clarification for the purpose of encouraging care coordination among providers, including clarification of what constitutes a Part 2 record and its applicability to ensure that non-Part 2 providers are not discouraged from caring for SUD patients. Yet, our members report that one of the greatest challenges to complying with the Part 2 rule is the lack of clarity about what providers are covered by Part 2 for all other stakeholders that interact with probable Part 2 programs. Since the determination of Part 2 applicability falls to the Part 2 provider, non-Part 2 providers and other lawful holders – including health insurers – are subject to compliance without knowing with any certainty when they are interacting with providers and patient records covered by Part 2.

This lack of clarity about what providers and records are subject to Part 2 presents a barrier to patients as well. While the definition of a Part 2 program includes individuals and entities that "hold itself out" as providing SUD diagnosis, treatment, or referral for treatment, there exists no requirement for Part 2 providers to identify themselves publicly as a Part 2 covered provider to patients and other stakeholders. Considering the intent of the Part 2 rules to encourage individuals to seek treatment for substance use disorders by imposing stricter requirements about disclosure of substance use-related information, it stands to reason that SUD patients would benefit from the ability to make informed choices about their selection of care provider, including whether that provider is subject to the Part 2 rules.

The Task Force strongly recommends that SAMHSA engage with impacted stakeholders and issue a report on potential mechanisms to reduce ambiguity in Part 2 program identification. The assessment should include an analysis of the excess compliance burden due to the lack of public identification of Part 2 programs and what information would be helpful for patients to make choices about SUD treatment providers.

II. Audit and evaluation

In its 2018 rule, SAMHSA finalized changes to specify that Part 2 disclosures are allowable to contractors, subcontractors, or legal representatives under §2.53 to carry out a Medicare, Medicaid, or CHIP audit or evaluation. In the preamble to the final rule (83 FR 246), SAMHSA uses the example of accountable care organizations (ACOs) and similar CMS-regulated health models as entities that may need to access all of the records, including Part 2 program records, in order to evaluate the impact of integrated care programs. **HHS should clarify how CMS will implement this authority in coordination with SAMHSA, and how those providers that meet the stated criteria may access the claims data for the purpose of audits and evaluation.** For example, CMS could provide model data-use agreements or a memorandum of understanding and clarify the process for eligible participants to make a request for this data from CMS for evaluation and audit purposes.

III. Education and Technical Assistance

Many stakeholders including the Medicaid and CHIP Payment and Access Commission have asked HHS to conduct a coordinated effort to provide education and technical assistance to providers, patients, and other entities around Part 2. Jessie's Law of 2018[1] provided that the Secretary of Health and Human Services, in consultation with appropriate experts, should identify and/or develop and disseminate model programs and materials for training a range of stakeholders concerning the permitted uses and disclosures of SUD records pursuant to Part 2, including training for patients and their families regarding their rights to protect and obtain information under the Part 2 standards and regulations. **The Task Force supports this requirement and encourages the Department to comply with producing and disseminating training materials in a timely manner.** These materials were to be disseminated no later than one year after the enactment of Jessie's Law in October 2018.

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The Task Force appreciates the opportunity to advise SAMHSA on this matter. Please contact HCTTF Senior Director Clare Pierce-Wrobel (clare.wrobel@hcttf.org or 202-774-1565) with any questions or to follow up to this letter.

Regards,

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[1] Pub. L. 115–271, title VII, §§ 7051–7053, Oct. 24, 2018, 132 Stat. 4017, 4018

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