March 17, 2017

VIA ELECTRONIC MAIL

Kana Enomoto  
Acting Deputy Assistant Secretary  
Substance Abuse and Mental Health Services Administration  
5600 Fishers Lane, Rockville, MD 20857

Re: Enforcement of SAMHSA-4162-20

The Health Care Transformation Task Force (“HCTTF” or “Task Force”)\(^1\) is writing to provide recommendations to the Substance Abuse and Mental Health Services Administration (“SAMHSA”) on the implementation of the Supplemental Notice of Proposed Rulemaking (SNPRM) issued with the SAMHSA-4162-20 Confidentiality of Substance Use Disorder Patient Records Final Rule (“Final Rule” or “Part 2 Regulations”), which implements changes to 42 C.F.R. Part 2.

As a leading private sector, multi-stakeholder consortium, the HCTTF is committed to adopting payment reforms that promote a competitive marketplace for value-based health care and allow health care organizations to move health care payment from a system that rewards volume of services to one that rewards value of care. Integration of behavioral health services and comprehensive care coordination is critical to delivering high-quality, patient-centered care for patients with substance use disorders.

The HCTTF generally supports the changes published earlier this year to the Part 2 Regulations including modifications that allow for consent to be executed to an intermediary. However, we believe that the Final Rule did not sufficiently address additional barriers to delivering high-value care under modernized care delivery models for the targeted patient population. Two specific concerns and recommendations for mitigation are provided below.

I. Effective Date of Supplemental Rule

The Final Rule did not update the historical definitions of health care operations to recognize advances in the U.S. health care delivery system and the critical role of third-party payers, contractors, and subcontractors in the payment and operation of health care services. To address this, SAMHSA proposed additional clarifications and modifications to the Part 2 rules to clarify the scope of disclosures permissible with consent under §2.33 in the SNPRM.

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\(^1\) The Task Force is a group of private sector stakeholders that wish to accelerate the pace of delivery system transformation. 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 the triple aim of better health, better care, and reduced costs. Our member organizations aspire to put 75 percent of their business into triple aim focused, value-based arrangements by 2020. We strive to provide a critical mass of policy, operational, and technical support from the private sector that, when combined with the work being done by CMS and other public and private stakeholders, can increase the momentum of delivery system transformation.
Without the effective clarifications the SNPRM proposes under Section 2.33 regarding permissible disclosures, routine and accepted functions of many health care entities could be found to be in violation of Part 2 following the Final Rule’s effective date and prior to the effective date of any finalized Supplemental Rule, with the possible period of noncompliance even more significant if the Supplement Rule is not finalized.

**We urge SAMHSA to finalize the Supplemental Rule as soon as possible and to implement simultaneous effective dates for both the Final Rule and Supplemental Rule.** Given the recent delay in effective date of the Final Rule provisions to March 21, 2017, SAMHSA should consider further delay of the effective date as necessary to harmonize the Final Rule and Supplemental Rule and provide a consistent effective date for the final policies.

**II. Definition of Health Care Operations**

Even if the Supplemental Rule is finalized as proposed, additional concerns remain with the definition of health care operations. The Final Rule included a restricted definition of “population health management” in the list of permissible services that a Qualified Service Organization could provide under the umbrella of health care operations, but explicitly rejected the inclusion of care coordination or case management in this list, citing a patient treatment component to those services. Further, the Final Rule also declined to define care coordination.

We believe that the decision to exclude or define care coordination and case management in either the list of permissible services or within the definition of population health management fails to appreciate the complexity and ever-evolving nature of population health management services. Under the Final Rule, population health management refers to increasing desired health outcomes and conditions through monitoring and identifying patients within a group; accountable care organizations (ACOs) and managed care organizations (MCOs) are listed as examples of units responsible for population health management, which could also be provided by other units such independent practice associations (IPAs).

In the regular operations of ACOs, MCOs, and IPAs, care coordination and case management are key functions that serve to increase desired health outcomes through monitoring and identifying patients within a group, consistent with the definition of population health management. **The Task Force recommends that the definition of population health management and/or the list of services permitted for the purposes of health care operations be amended to include care coordination and case management.**

Please contact HCTTF Director, Payment Reform Models Clare Wrobel (clare.wrobel@hcttf.org or 202-774-1565) with any questions about or to follow up to this letter.

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