February 12, 2019

VIA ELECTRONIC MAIL

Roger Severino
Director, Office of Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Request for Information on Modifying HIPAA Rules to Improve Coordinated Care

Dear Inspector Levinson:

The Health Care Transformation Task Force (HCTTF or Task Force) thanks the Office of Civil Rights (OCR) for seeking assistance from the public in identifying provisions of the Health Insurance Portability and Accountability Act (HIPAA) that may impede the transformation to value-based health care or that limit or discourage coordinated care among individuals and covered entities without meaningfully contributing to the protection of the privacy and security of individuals' protected health information.

The Task Force is a consortium of over 40 private sector stakeholders that support 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. Our member organizations aspire to have 75 percent of their business in 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 HHS and other public and private stakeholders, can increase the momentum of delivery system transformation.

In this letter, the Task Force responds to the potential modifications to rules as posed in the Request for Information and provides comment on the provisions of the HIPAA rules that

present obstacles to the transformation of health care payment and care delivery away from fee-for-service to a value-based health care system.

I. Promoting Information Sharing for Treatment and Care Coordination

In this RFI, the OCR offered potential modifications to the HIPAA rules currently under consideration to promote coordinated care and value-based health care, including creating new requirements, exceptions, and more express regulatory permissions for certain data-sharing relationships. The Task Force offers strong support for the proposal to increase public outreach and education – including for patients – on existing provisions of the HIPAA rule that permit uses and disclosures of PHI for care coordination and/or case management, in addition to any modifications to existing policy.

A. Expand sub-regulatory guidance regarding the applicability of HIPAA

Our members report inconsistent interpretation of the rule and therefore there is a perception that Covered Entities tend to implement data-sharing policies more narrowly than envisioned under HIPAA. For example, the RFI contemplates adding an express regulatory permission for Covered Entities to disclose PHI to social service agencies or community-based support programs, yet this is already a permitted disclosure. OCR should address the inconsistent implementation of existing provisions by offering not only education but abundant sub-regulatory guidance on the legal compliance requirements under HIPAA. **We urge OCR to expedite and regularly update Frequently Asked Questions guidance documents and/or commentaries in response to recurrent questions regarding common provider circumstances to clarify which activities are and are not permitted.** If OCR were to provide more frequent and timely sub-regulatory guidance, this in itself could reduce some of the regulatory burden of compliance. The guidance should include best practices to give covered entities and non-covered entities examples of how others are successfully sharing information in compliance with HIPAA.

B. Patient outreach and education

We strongly encourage OCR to facilitate greater and improved education to health care providers and to patients and their caregivers regarding the provisions of HIPAA that permit uses and disclosures of PHI. Educational materials and training should be translated for real-life application. Information should be provided in ways that are accessible and understandable by all, including in multiple languages and for users with physical disabilities. OCR should have a strong infrastructure in place that is easily accessible to address questions and concerns from patients and families. Outreach and education should also include a focus on how state and other federal laws interact with HIPAA, including situations where the Privacy Rule defers to states and other federal laws that include even stronger privacy protections.

II. Removing Regulatory Obstacles and Reducing Regulatory Burdens To Facilitate Care Coordination and Promote Value-Based Health Care Transformation

The success of potential modifications and clarifications to the HIPAA rule on advancing care coordination will be dependent on consistent terminology and definitions of permissible activities. Many of these terms – such as "care coordination" and "case management" – have meaningful definitions regulated under separate HHS divisions including provisions of the Stark law, Anti-Kickback Statute, MACRA, and 42 CFR Part 2. The Task Force encourages OCR to work together with CMS, OIG, and SAMHSA to establish clear definitions and bright line standards for permissible activities under payment arrangements that take into account the volume or value of services, while protecting privacy of protected health information.

A. Align privacy rules and definitions

We have previously provided recommendations to the Substance Abuse and Mental Health Services Administration (SAMHSA) in March 2017[1] 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), which implemented changes to 42 C.F.R. Part 2. We commented to SAMHSA that neither the Final Rule nor the additional clarifications and modifications to the Part 2 rules in the SNPRM adequately 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.

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 is defined as 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.

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[1] https://hcttf.org/2017-3-20-task-force-provides-recommendations-to-samhsa-regarding-42-cfr-part-2/

The Task Force recommended to SAMHSA 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. The Task Force recommends that OCR coordinate with SAMHSA to ensure consistency in definitions pertaining to population health management activities. Any changes made to the HIPAA Rule should also be accompanied by corresponding changes to other regulations with common definition-based exceptions – including the physician self-referral law, Anti-Kickback Statute, and the Quality Payment Program rules – to ensure consistency of approach and enforcement across all HHS regulated programs. HHS will move closer to its stated goal of the "regulatory sprint to coordinated care" and reduce provider burden by bringing these programs into greater definitional alignment.

III. Conclusion

The Task Force appreciates the opportunity to advise OCR regarding the impact of the HIPAA Privacy regulations on value-based transformation. We believe that, with proper protections in place, improvements to information sharing is an important tool in facilitating improved care coordination and will support improvements in patient experience and outcomes.

Please contact HCTTF Executive Director Jeff Micklos (jeff.micklos@hcttf.org or 202.774.1415) with questions related to this statement.

Respectfully,

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