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April 5, 2016

Ms. Kana Enomoto  
Principal Deputy Administrator  
Substance Abuse and Mental Health Services Administration  
U.S. Department of Health and Human Services  
Attn: SMAHSA-4162-20  
5600 Fishers Lane, Room 13N02B  
Rockville, MD 20857

***RE: SAMHSA-4162-20; Confidentiality of Substance Use Disorder Patient Records, Proposed Rule***

Dear Administrator Enomoto:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the proposed revision to the regulation governing the confidentiality of substance use disorder patients' records. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), the proposed revision will allow greater flexibility in sharing patient information to support new models of integrated care that require information exchange for care coordination, rely on an electronic infrastructure for managing and exchanging patient information, and focus on performance measurement and improvement within the delivery system.

The AHA believes that the proposed revision would not be an improvement over the current requirements as it does nothing to eliminate the barriers that significantly impede the robust sharing of patient information necessary for effective clinical integration contained in the 42 CFR Part 2 regulation (Part 2 regulation). **Instead, we urge full alignment of the Part 2 regulation with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulation as the proper and effective solution to eliminating the existing barriers to the sharing of patient information essential for care coordination, compatible with electronic exchange of information and supportive of performance measurement and improvement.**

In contrast, SAMHSA asserts that the statute underlying the Part 2 regulation provides more stringent federal protections than HIPAA, including a requirement for patient consent to share information. While we understand that it is not within SAMHSA's authority to circumvent the existing statutory structure, we believe that the agency could do much more immediately to align



these two sets of requirements, even within the limitations of the current statute. Moreover, while reform of the statute remains the purview of the legislative branch, we urge SAMHSA to prioritize efforts aimed at educating Congress about the significant burdens the existing statutory framework imposes for the integration of behavioral health and other medical care and to work directly with them to resolve the statutory conflicts that prevent full alignment of the federal requirements for privacy and confidentiality of health information related to behavioral health with the HIPAA requirements that govern all other patient health information. Such effort directly undertaken by SAMHSA would do more to facilitate the sharing of information necessary for coordinated care delivery and improved health outcomes for all patients than the nominal revisions the agency currently proposes to make in the Part 2 regulation.

### **THE HIPAA PRIVACY STRUCTURE BETTER PROMOTES ROBUST INFORMATION SHARING ESSENTIAL FOR CLINICAL CARE COORDINATION AND POPULATION HEALTH IMPROVEMENT**

**The AHA has long advocated that the HIPAA requirements be the prevailing nation-wide standard for protecting the privacy and security of all patient information.** While by no means without its own regulatory impediments to the robust use and disclosure of patients' personal health information (PHI) necessary to support clinical integration and population health improvement, the HIPAA regulation generally permits covered entities, like hospitals and other health care providers, to share PHI for purposes of treatment, payment and health care operations without having to obtain each individual patient's authorization.

**The AHA also remains unwavering in its support for full federal preemption under HIPAA.** Because HIPAA currently does not preempt other federal or state laws that require information be treated and handled differently, of which the Part 2 regulation is a prime example, the resulting patchwork of health information privacy requirements remains a significant barrier to the robust sharing of patient information necessary for coordinated clinical treatment, improving the quality of care and maintaining population health. In addition, the patchwork of differing requirements poses significant challenges for providers' use of a common electronic health record that is a critical part of the infrastructure necessary for effectively coordinating patient care and maintaining population health.

### **THE SEPARATE PART 2 PRIVACY STRUCTURE IS A SIGNIFICANT BARRIER TO INTEGRATING BEHAVIORAL AND PHYSICAL HEALTH CARE**

The separate privacy structure under 42 CFR Part 2 especially creates challenges for the integration of behavioral and physical health care simply because patient data related to behavioral health cannot be handled like all other health care data. Estimates are that one in four Americans experiences a behavioral illness or substance use disorder each year, and the majority of these individuals have a comorbid physical health condition. Moreover, primary care has become the prevailing location for patients to receive treatment that addresses all their health needs, behavioral as well as medical. Evidence confirms that integrating mental health, substance abuse and primary care services produces the best outcomes and proves the most effective approach to caring for people with multiple health care needs.

Furthermore, at the highest stage of care integration, the focus is not merely on improving medical outcomes for individual patients but managing population health while reducing total costs for the overall health care delivery system. To meet the needs of the many individuals with complex health needs, however, providers must be able to share patient behavioral health information as easily as information related to physical health for purposes of treatment, payment and health care operations, (i.e., without having to obtain each individual patient's authorization as HIPAA permits).

The requirement in the Part 2 regulation for individual patient consents to make sharing of behavioral health information permissible seems to overemphasize the social harms that disclosing such clinical information is perceived to create at the risk of medical harms and overdose deaths that are a consequence of poor coordination of care for such patients. Moreover, because the requirement to obtain individual patient consents significantly complicates the sharing of important patient information essential for coordinating care and population health improvement, it contributes to higher health care costs for patients with complex health needs, who already are among the highest-cost utilizers in health care. Permitting providers to handle and treat patient data related to behavioral health as simply another part of a patient's health care data protected by HIPAA is an critical component of a demonstrated more effective approach to caring for and achieving the best outcomes for all patients.

#### **THE PROPOSED REVISION DOES NOT REMOVE EXISTING OBSTACLES THAT IMPEDE ROBUST INFORMATION SHARING**

The proposed revisions to the Part 2 rule do not adequately respond to the need to better integrate patient information related to behavioral health care with patient information related to other medical conditions for effective care coordination and population health improvement. In fact, the proposed revisions maintain the status quo of generally requiring individual patient consents for disclosure, which requires health care providers to maintain a strict separation of a patient's behavioral health-related data from other patient data.

The Part 2 regulation remains broadly applicable to treatment programs and providers in spite of the changes SAMHSA proposes in the definition of the regulation's applicable scope. SAMHSA's proposal would carve out general medical facilities and medical practices from the scope of the Part 2 regulation in what might seem initially like a broad general carve out. However, SAMHSA immediately restricts that carve out. Specifically, general facilities and practices are excluded from the scope of the Part 2 regulation, and thereby from complying with the significant regulatory constraints imposed on sharing a patient's behavioral health data, *only if* they do not hold themselves out as providing substance use disorder diagnosis, treatment or referral for treatment and the primary function of their medical personnel or other staff is not the provision of, and they are not identified as providing, such services. In the current care environment, where there is expanding emphasis on integration and coordination of behavioral health care with physical health care and where the prevailing location for delivery of that care is the general medical facility or medical practice, SAMHSA's proposal effectively reduces the regulation's flexibility for sharing patient information. That is because the severe constraints and significant burdens on sharing a patient's behavioral health information the regulation imposes

Kana Enomoto

April 5, 2016

Page 4 of 4

are likely to apply to many more treatment settings and providers. This is just one prominent example of the inflexibility that continues to permeate the Part 2 regulation despite SAMHSA's stated objective to update and modernize them to support new models of care.

**Both patients and providers would best be served if the current proposal is withdrawn and reevaluated to determine how to best align the Part 2 regulation with the current HIPAA rules that permit patient information to be used and disclosed for treatment, payment and health care operations without having to obtain individual patient consents. It also will be essential for SAMHSA to work with Congress to eliminate any barriers in the statute underlying the Part 2 regulation that prevent full alignment.** Applying the same requirements to all patient information – whether behavioral- or medically-related – would support the appropriate information sharing essential for clinical care coordination and population health improvement in today's patient care environment, where behavioral and medical health care are integrated to produce the best outcomes for all patients.

If you have any questions about our recommendations, please contact Lawrence Hughes, assistant general counsel, at [lhughes@aha.org](mailto:lhughes@aha.org) or (202) 626-2346.

Sincerely,

/s/

Melinda Reid Hatton  
Senior Vice President and General Counsel