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April 11, 2016

Kana Enomoto  
Principal Deputy Administrator  
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

Dear Ms. Enomoto,

On behalf of its member companies, the Electronic Health Record (EHR) Association is pleased to submit comments on the Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) Substance Abuse Confidentiality Regulations (42 CFR Part 2) Proposed Rule.

#### Comments

Since the promulgation of the 42 CFR Part 2 regulation in 1975, there have been significant changes in the healthcare continuum that have impacted treatment, information exchange, and delivery of care. We support HHS' intent to revise the regulations to align with the current healthcare system and provide a framework to facilitate electronic exchange of substance abuse health information, while ensuring appropriate security and privacy protections. We support the department's recognition of the privacy concerns associated with individuals with substance abuse health conditions, as breach of information can often lead to various consequences. The overall aim must remain to promote and encourage patients to seek treatment and participate in other legitimate health programs by offering security and privacy protections as applicable to electronic exchange.

While the intent to improve interoperability is applauded, we believe the proposed changes will introduce significant complexity to the current workflow. Changes around sharing data with population health management systems should be carefully evaluated, recognizing potential conflicts with other state or federal laws that place restrictions on sharing sensitive data. The proposed changes to the consent section seem cumbersome. We have concerns in particular over the changes to the "Amount and Kind" section to allow patients to explicitly define restrictions on the substance abuse information to be disclosed. The systems today focus on supporting basic choices, and recent technical standards to support granular consent have been limited to document-level, and requiring the HIT system to support item-level restrictions (or

tagging) would significantly hamper interoperability, which goes against the spirit of this revision. In addition to the technical challenges, the agency should recognize other barriers to this implementation, such as the lack of harmonization in definition of sensitive health conditions, complexity in navigating individual state regulations, challenges around mapping to clinical codes and lack of a standardized service discovery mechanism to ensure capability of exchanging systems to evaluate the ability to receive and interpret a tagged document. The section for security seemed light, keeping in mind that the proposed privacy and consent changes have to be achieved through security mechanism and technical or administrative controls. We ask that the agency review existing federal security requirements that certified health IT systems such as certified EHRs are subjected to, such as the HIPAA security rule and align proposed changes to existing requirements.

To summarize, the measures to facilitate interoperability and exchange of sensitive information must recognize the privacy and security controls implementation required. We believe the proposed changes must be reassessed by keeping in mind the development efforts needed by the EHR, or other certified health IT systems to support the proposed privacy changes, and the operational overhead to the users.

Sincerely,

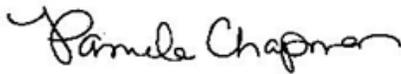


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Chair, EHR Association  
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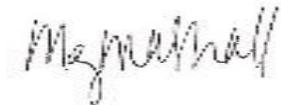
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### About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit [www.ehrassociation.org](http://www.ehrassociation.org).