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October 25, 2019

Elinore F. McCance-Katz, M.D., Ph.D.
Assistant Secretary for Mental Health and Substance Use
The Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane, Room 17E41
Rockville, MD 20857

Dear Dr. McCance-Katz,

Thank you for the opportunity to comment on the Substance Abuse and Mental Health Services Administration's proposed changes to the Confidentiality of Substance Use Disorder Patient Records regulations. On behalf of the Electronic Health Record (EHR) Association, we are pleased to share our input.

The EHR Association's 33 member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our core objectives focus on collaborative efforts to accelerate health information and technology adoption, advance information exchange between interoperable systems, and improve the quality and efficiency of care through the use of these important technologies.

Our detailed feedback is included with this letter. We find that SAMHSA's proposals provide much-needed clarity and specificity on the applicability of the regulations, as well as where responsibilities of non-Part 2 providers lie. However, while we appreciate these moves to bring 42 CFR Part 2 in alignment with other privacy rules, there is still more work to be done to align with HIPAA and across agencies.

Our feedback also explains our support for the proposed changes as stated, without introducing additional reliance upon or requirement for the Data Segmentation for Privacy (DS4P) standard. Because there are still pervasive concerns about DS4P's readiness for deployment at scale, we hope SAMHSA will continue to work with stakeholders on updates to the standard.

We appreciate this opportunity to share the insights and expertise of our members, who believe that health IT in general, and EHRs in particular, can play an important role in enabling access to all relevant healthcare data, thus improving clinical decision-making by the clinician, as well as the patient. Well-coordinated care and appropriate confidentiality protections are not mutually exclusive, and the EHR Association looks forward to continuing to support SAMHSA's efforts to better align 42 CFR Part 2 with the needs of individuals with substance use disorder and of the clinicians who treat them.

Sincerely,

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Chair, EHR Association
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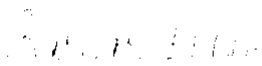

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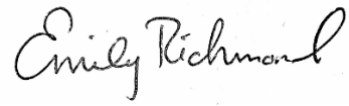

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About the HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 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.ehra.org.

Section III.A., Definitions

We propose to amend and clarify the definition of "Records" in § 2.11, in a manner that aligns with the proposed revision to § 2.12 described above.

EHRA comments:
While we appreciate the attempt to bring 42 CFR Part 2 in alignment with other privacy rules, there is still more work to be done to align with HIPAA and across agencies. A paper-based workflow point of view is outdated, and runs counter to burden-reduction efforts.

Section III.B., Applicability

SAMHSA proposes to amend § 2.12 to clearly state in the regulatory text that the recording of information about a SUD and its treatment by a non-part 2 entity does not, by itself, render a medical record subject to the restrictions of 42 CFR part 2, provided that the non-part 2 entity segregates any specific SUD records received from a part 2 program (either directly, or through another lawful holder). SAMHSA believes this proposed language would encourage part 2 programs and non-part 2 providers to deliver better and safer coordinated care, while also protecting the confidentiality of individuals seeking such care. SAMHSA explains this proposal more fully in Section III.B.

EHRA comments:
The EHR Association strongly supports SAMHSA's proposals to clarify applicability of 42 CFR Part 2 restrictions as exclusively focused on substance use disorder (SUD) records created by Part 2 providers, and not on records created by non-Part 2 providers in their direct care for patients with a SUD (provided non-Part 2 providers maintain separation of records received from Part 2 providers). These proposals provide much-needed clarity and specificity on the applicability of the regulations, as well as where responsibilities of non-Part 2 providers lie. The approach strikes the right balance between promoting coordination of care and protecting the privacy of SUD patients within the scope of current law.

We do ask for further guidance for situations in which previously-received Part 2 records cannot be segregated by the non-Part 2 provider. We would additionally appreciate clarification on whether there is a distinction (or conversely, ambiguity) between what constitutes the legally recognized medical record, versus shared information that is structured and record-like. In other words, at what threshold of structure and formality of conveyance does "information" become "record?"

Section III.C., Consent Requirements

SAMHSA proposes to amend § 2.31, to allow patients to consent to the disclosure of their information to a wide range of entities, without naming the specific individual receiving this information on behalf of a given entity; special instructions would apply with respect to consents for disclosure of information to

information exchanges and research institutions. We believe this proposal would give patients the ability to apply for and access federal, state, and local resources and benefits more easily, (e.g., social security benefits; local sober living or halfway house programs).

EHRA comments:
In keeping with clarifications under the previous 2017 rulemaking, which allowed for specification of organizations and not individuals for treatment related disclosures, the EHR Association supports this further clarification and convergence to allow organization names in all cases. Previous interpretation often resulted in the far more burdensome stipulation and management of individual persons providing care in the statement of consent.

Section III.E., Disclosures Permitted with Written Consent

SAMHSA proposes amendments to § 2.33 to expressly allow disclosure to specified entities and individuals for 17 types of payment and health care operational activities. Although SAMHSA believes these activities were already permitted by the regulation, we have received feedback from stakeholders that there remains some confusion on these points. Therefore, we believe it necessary to more clearly state this regulatory permission in the regulatory text, to avoid any further confusion.

EHRA comments:
The EHR Association appreciates that the proposal identifies 17 examples of activities that are permitted for the purpose of "payment and healthcare operations." We recommend further defining the process and expectations for activities that are not encompassed by 17 examples.

Section III.F., Disclosure to Prevent Multiple Enrollments

SAMHSA seeks to reduce barriers to care coordination for patients with SUD by proposing to amend § 2.34 to allow non-opioid treatment providers (e.g., non-part 2 providers who nevertheless manage care for patients with SUD from time to time) to access central registries.

EHRA comments:
In theory, we strongly support access to the PDMP by clinical providers; however, questions have been raised about potential liability for non-Part 2 providers who do not check the PDMP, resulting in potential harm.

We encourage SAMHSA to recognize the need to educate non-opioid treatment programs (OTPs), as this proposal would open access to a group of clinicians who are not familiar with the PDMP program and its benefits and limitations.

Section III.G., Disclosure to Prescription Drug Monitoring Programs

SAMHSA proposes to add new § 2.36 to permit opioid treatment programs (OTPs) to disclose dispensing and prescribing data, as required by applicable state law, to prescription drug monitoring programs (PDMPs), subject to patient consent.

EHRA comments:
Under CMS' proposed creation of a new benefit area and provider type for OTPs, the requirement that an OTP providing Medication Assisted Treatment (MAT) must verify that the patient is not already receiving an active course of MAT from another provider raises questions of compatibility

with Part 2. Verification likely will be done via electronic means, through an external registry. It may also be accomplished through a Health Information Exchange (HIE) in which both the OTP and registry participate.

This raises the question: does the query by the OTP provider require explicit patient consent for the OTP provider to perform the query? Since the identity of the OTP provider itself reveals that the patient is in a Part 2 covered program, it would otherwise seem to necessitate patient consent; however, that requirement here -- giving the patient the option to refuse consent -- would undermine the intent of and safeguards of the MAT verification requirement. It then seems unclear which statute takes precedence and creates a compliance conundrum for Part 2 providers as well as continuing reticence by both Part 2 providers and non-Part 2 recipients to share data falling under the purview of Part 2.

A similar conundrum still exists when weighing Part 2 requirements and clinical reconciliation requirements for any (Part 2 or non-Part 2 covered) providers using Certified EHR Technology (CEHRT) while participating in Promoting Interoperability under CMS's MACRA Quality Payment Program or for Eligible Hospitals and Critical Access Hospitals. Since the reconciliation of clinical data – problems, medications and medication allergies – in this case is electronic, resulting in the import of said data into the receiving EHR, we would welcome clarification that this data can be electronically transcribed without need for manual retyping in order to comply with the intent of the proposed distinction between information from a Part 2 provider and records from such a provider. If the information can be transcribed manually without inheriting full Part 2 restrictions, then in the case of clinical reconciliation, it would be consistent to allow CEHRT systems to do so electronically.

As with our other comment, above, it should be noted that this also suggests a conflict of program guidelines between these proposed Part 2 rules and the CMS guidance on the use of CEHRT systems, and likewise, without clear reconciliation, organizations will be wary of participation if their legal footing is not clear.

The previous paragraphs' points may then tempt a recommendation that Data Segmentation for Privacy (DS4P) standard be more strongly encouraged or required. EHRA believes that would be a mistaken path toward resolution of the conundrums given the still immature state of the DS4P standard and well-documented concerns with its practical feasibility without further normative consensus. We therefore support the proposed changes as stated, without introducing additional reliance upon or requirement of DS4P at this time.

Section III.H., Medical Emergencies

SAMHSA proposes to amend to § 2.51 to allow disclosure of patient information to another part 2 program or other SUD treatment provider during State or Federally declared natural and major disasters. SAMHSA believes this proposal would reduce the burden of disclosure requirements both for patients to receive, and for clinicians to provide, care that may not be otherwise feasible during natural and major disasters, ensuring that patients can continue to receive on-going and appropriate care.

EHRA comments:
The EHR Association strongly supports this clarification. This is a prudent change for operation during declared emergencies and disasters. It may also be helpful to underscore other responsibilities, such as recipient obligations to not redisclose without further or other explicit consent, or to not disclose for other than stated purpose.

DS4P Standard

SAMHSA recognizes and encourages the further development of DS4P standards, and the adoption by providers of EHR systems that meet those standards. The current proposal for revising § 2.12 does not, however, impose on non-part 2 entities any new requirement for data segmentation as a practice, nor does it establish any new standards or requirements for EHR technology.

EHRA comments:
The EHR Association appreciates that SAMHSA is not requiring use of DS4P standard; there are still pervasive concerns about its readiness for use at scale.

However, we recognize that privacy policy and implementing standard solutions to respect privacy are of paramount importance as healthcare delivery and consumer products increasingly move to the digital era. We include here a few notes about EHR developers' concerns about DS4P, in the hopes that SAMHSA will continue to work with stakeholders on updates to the standard.

Safety
If portions of the EHR are segmented, how will clinicians be able to trust the data, and trust that they are making the right care decisions for their patients? Further, to what extent is segmented sensitive data allowed to be used by systems to promote patient safety and prevent adverse events through functionality like Clinical Decision Support and analytics that inform clinicians on a patient's risk of morbidity? This is especially important because FDA medical device guidance requires visibility into how IT systems arrive at their recommendations, which isn't necessarily possible in a world of segmented data. Updates to the DS4P standard will need to address these concerns that our users have raised directly.

Trust and appropriate use by recipients
While the DS4P standard details methodology of how documents, data classes, and data elements can be tagged with sensitivity, it does not detail how recipient systems should handle tagged data, and the scenarios under which it is appropriate to use/disclose data tagged as sensitive, both within system processes and in end-user workflows. There is little value in taking the time to tag differing levels of sensitivity if there is no assurance that downstream systems will respect the sensitivity of that data as expected. Updated DS4P standards will need to address this need by setting expectations for how data can be used/displayed by downstream systems for different sensitivity levels.

Burden for users
Privacy rules and restrictions are not codified by jurisdictions in machine-consumable formats and often do not include context-specific value sets. As a result, it is impossible for implementing health IT systems to automatically tag data as sensitive, and automatically respect privacy rules. Doctors, nurses, and other end-users will therefore need to manually tag data elements as sensitive, leading to clunky workflows and increased documentation burden. Updated DS4P standards will need to find a way to automate the tagging process to prevent added burden on users.