EHRA
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January 30, 2023

Melanie Fontes Rainer
Director, Office for Civil Rights
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Miriam Delphin-Rittmon, Ph.D.
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
U.S. Department of Health & Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Rainer and Dr. Delphin-Rittmon,

On behalf of our 30 member companies, the HIMSS Electronic Health Record (EHR) Association is pleased to provide feedback on the Confidentiality of Substance Use Disorder (SUD) Patient Records Notice of Proposed Rule Making (NPRM). We appreciate the opportunity to provide comments on the proposal to modernize the privacy regulations of 42 CFR Part 2 to better support patient care as intended by section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

As a national trade association of EHR developers, EHR Association member companies serve the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. Together, we work to improve the quality and efficiency of care through the adoption and use of innovative, interoperable, and secure health information technology.

The EHR Association applauds the Department's objective in this NPRM to permit the uses and disclosures of Treatment, Payment, and Operations (TPO), as those terms are defined in HIPAA, with written patient consent. Permitting such uses and disclosures has been the subject of EHR Association advocacy for many years, as doing so will better enable providers to leverage the sophisticated interoperability tools of EHRs to holistically care for patients with substance use disorders.

We offer the following considerations regarding the NPRM.

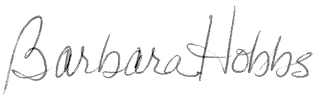
Sincerely,

David J. Bucciferro
Chair, EHR Association
Foothold Technology

William J. Hayes, M.D., M.B.A.
Vice Chair, EHR Association
CPSI

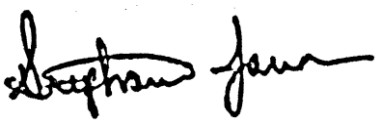
HIMSS EHR Association Executive Committee

Leigh Burchell
Altera Digital Health

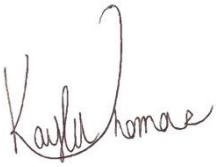


Barbara Hobbs
MEDITECH, Inc.

Cherie Holmes-Henry
NextGen Healthcare



Stephanie Jamison
Greenway Health



Kayla Thomas
Oracle Cerner

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

Effective and Compliance Dates

Regarding the proposed 60-day effective date and 22-month compliance date, the EHR Association recommends that the Department clarify whether healthcare organizations will be required to wait until the compliance date to begin using and disclosing Part 2 records for HIPAA treatment, payment, and operations if they have otherwise met the revised regulatory requirements (e.g., updating Notices of Privacy Practices, obtaining patient consent, etc.).

We recommend specifying that organizations will be permitted to use and disclose Part 2 records for HIPAA treatment, payment, and operations as soon as they meet the requirements of the final rule.

Definitions – Intermediary

The EHR Association agrees with the definition of "intermediary" provided. However, we recommend the Department clarifies the example in the final rule, as we do not believe the example fits the definition as stated. An EHR developer would not be an intermediary as cited in the example in the preamble. In this scenario, the EHR developer would only be supplying interoperable software to two healthcare organizations that independently deploy that software to enable exchange with each other. If the organizations do not transmit the record to the developer of the EHR software in that process, the EHR developer is not an intermediary. In fact, there would be no intermediary in that situation – the organizations are engaging in exchange directly with each other.

Definitions - Records

It is unclear how the Department expects Covered Entities that are the recipients of Part 2 data to apply protections of Part 2 to their records once the data has been reconciled and incorporated into the Covered Entity's local record.

For example, suppose Healthcare Organization A (a non-Part 2 Covered Entity provider) received two Summary Care Records (SCRs). One from a Part 2 program and one from Healthcare Organization B (also a non-Part 2 provider). Both SCRs note that the patient in question uses methadone. The provenance of where Organization B learned that the patient uses methadone is unknown, as current health IT standards for exchanging provenance information only include the "last hop" (i.e., Organization B is the source of the information). The Covered Entity would reconcile the records it received into its local record by documenting in the medication list that the patient uses methadone.

In this scenario, for clarity under current rules, would Part 2 protections apply only to the whole of the SCR received from the Part 2 program as it may be included in Organization A's medical record, or would Part 2 protections apply to the individual medication item reconciled into Healthcare Organization A's medical record? In either case, upon redisclosure, under the proposed rule, would Part 2 protections

continue to apply? Would Organization A be permitted to redisclose the patient's methadone use for TPO under HIPAA rules, and could Organization A redisclose the patient's use of methadone they originally received from a Part 2 program without applying the proposed statement indicating that the record being disclosed is a Part 2 record?

We ask the Department to clarify whether received Part 2 records can be reconciled into the records of the Covered Entity and retain their Part 2 protections from redisclosure for legal proceedings, or whether the received Part 2 records can be "fully" reconciled and no longer require being marked as Part 2 information.

In the above example, if a Covered Entity is unaware that the original source of a portion of a patient's record is from a Part 2 program upon receipt, it should not be expected to apply Part 2 protections or restrictions to the record.

Similarly, suppose the re-disclosing organization is unable to indicate that the origination of a certain portion of the record is from a Part 2 program. In that case, it should still be permitted to redisclose the information for TPO to ensure patient safety and continuity of care. Not permitting this disclosure would withhold vital information from clinicians.

The EHR Association urges the Department to continue to engage with the standards development community to enhance provenance standards to enable "multiple hops" or "original documentation location" to be specified so that protections can continue to be applied to redisclosed data accurately.

Confidentiality Restrictions and Safeguards

The EHR Association believes that a special set of rules for the security of 42 CFR Part 2 regulated records is unnecessary. Applying a consistent set of security expectations across PHI and Part 2 records will reduce burden and clarify compliance expectations for entities that provide healthcare and Part 2 programs.

HIPAA requires healthcare organizations to evaluate the risks and impacts of a potential breach or disclosure and sets expectations that entities would implement appropriate safeguards to mitigate those risks. Thus, if organizations consider Part 2 records more sensitive, HIPAA would expect the implementation of safeguards that appropriately match the heightened breach sensitivity.

Consent Requirements

The EHR Association requests that the Department clarify whether consent could be broadly obtained and apply to a patient's entire historical record under the stewardship of a Part 2 program. We note that it could be technically challenging to implement a "cutoff date" for which records are treated as having heightened Part 2 protections versus which may be disclosed according to HIPAA's privacy and security rules with a patient's consent.

We recommend permitting organizations to collect consent from patients to use and disclose their entire historical record for treatment, payment, and operations as those terms are defined in HIPAA and according to the HIPAA privacy and security rules.

Further, we note that while the intent of this rulemaking to create a single consent is valuable, there remains a variation in requirements for the release of information across states, which presents additional complications. The adoption of a federal electronic consent standard would significantly ease this burden.

Uses and Disclosures Permitted with Written Consent

The EHR Association enthusiastically supports "permitting covered entities and business associates to use and redisclose Part 2 records in accordance with the standards that apply to PHI in the Privacy Rule and permitting Part 2 programs to use, disclose, and redisclose Part 2 records for TPO purposes when the records are obtained under a written consent given once for all future TPO uses and disclosures."

This expanded ability to use and disclose Part 2 records will enable greater care coordination and continuity of care between provider organizations, which will contribute to improved patient outcomes.