

May 6, 2021

The Honorable Xavier Becerra
Secretary of Health & Human Services
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

Ms. Robinsue Frohboese
Acting Director and Principal Deputy
Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Becerra and Acting Director Frohboese,

The Electronic Health Record (EHR) Association appreciates the opportunity to provide input to the proposed modifications to the Standards for the Privacy of Individually Identifiable Health Information (Privacy Rule) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act). Privacy Rule updates are clearly needed given the extraordinary advancements in health information and technology since passage of these laws – advancements to which our members are proud to have contributed.

The EHR Association’s nearly 30 member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our focus is on collaborative efforts to accelerate health information and technology adoption, assist member companies with regulatory compliance, advance information exchange between interoperable systems, and improve the quality and efficiency of patient care through the use of technology.

A key concern in our comments is that the Privacy Rule should not define an EHR contrary to common industry usage. Whether health data is managed in an EHR or in other health IT is irrelevant to the goal of protecting patient privacy. OCR’s policy will be better served by identifying what electronic health information must be protected, rather than what system stores the data.

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Cerner Corporation	Epic	Lumeris	Nextech	

Thank you for this opportunity to share our experiences and expertise.

Sincerely,



Hans J. Buitendijk
Chair, EHR Association
Cerner Corporation



David J. Bucciferro
Vice Chair, EHR Association
Foothold Technology

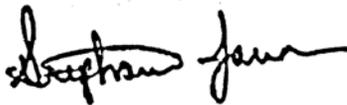
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Electronic Health Record Association
Response to HHS NPRM to Modify the Standards for the
Privacy of Individually Identifiable Health Information

III.A.9 Request for Comments

a. Whether the Department’s proposed definition of EHR is too broad, given the context of the HITECH Act, such that the definition should be limited to clinical and demographic information concerning the individual.

You propose to define EHR as follows:

Electronic health record means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff. Such clinicians shall include, but are not limited to, health care providers that have a direct treatment relationship with individuals, as defined at § 164.501, such as physicians, nurses, pharmacists, and other allied health professionals. For purposes of this paragraph, “health-related information on an individual” covers the same scope of information as the term “individually identifiable health information” as defined at § 160.103.

As noted in the proposal, this definition would incorporate systems not commonly labeled as EHRs in the industry today, including laboratory information systems (LIS) or payer systems. We are concerned that a broad definition which does not align with how the term is more commonly used in the industry will have unintended consequences.

Industry use of the term EHR more closely matches the definition of a “qualified electronic health record” in the HITECH Act:

(13) QUALIFIED ELECTRONIC HEALTH RECORD.— The term ‘qualified electronic health record’ means an electronic record of health-related information on an individual that—

- (A) includes patient demographic and clinical health information, such as medical history and problem lists; and*
- (B) has the capacity—*
 - (i) to provide clinical decision support;*
 - (ii) to support physician order entry;*
 - (iii) to capture and query information relevant to health care quality; and*
 - (iv) to exchange electronic health information with, and integrate such information from other sources.*

For example, our trade association of electronic health record developers uses this definition of an EHR:

“EHR” means a longitudinal electronic record of patient health information produced by encounters in one or more care settings anywhere along the continuum of care; including patient demographics, progress notes, problems, medications, vital signs, past medical history,

immunizations, laboratory data, and radiology reports with the ability to independently generate a complete record of a clinical patient encounter and sufficient data granularity to support clinical decision support, quality management, clinical reporting, interoperability, population health management, and data analytics.

OCR's proposed definition better aligns with the more general industry term "health information technology."

Attempting to repurpose the term "EHR" from how it is currently used in the industry, to expand to cover all systems that might house electronic health information (EHI), will introduce competing definitions, unclear policies, and unintended consequences as further regulation is established. OCR's focus should be on defining the policies and protections for patient data, not the systems that may or may not capture it. OCR should set clear expectations for the treatment of electronic health information; any system used by covered entities in processing that information should then meet the same expectations.

b. Whether an electronic record can only be an EHR if it is created or maintained by a health care provider, or whether there are circumstances in which a health plan would create or maintain an EHR.

Systems used by health plans are not typically considered EHRs. However, as explained above, we suggest that HIPAA should focus on electronic health information itself, regardless of what electronic system is used to manage data or the purposes for which data is collected and used. Ensuring protection of a patient's privacy is the goal, whether their data is managed in an EHR or another form of health IT.

c. Whether the Department should instead define EHRs to align with the scope of paragraphs (1)(i) and (2) of the definition of designated record set.

This definition would also not match industry usage of the term EHR, and would have unintended consequences. As explained above, we recommend focusing on the data, rather than the definition of a system that maintains that data.

d. Whether the proposed definition of EHR includes PHI outside of an electronic designated record set, whether it should, and examples of such PHI.

EHR systems likely maintain PHI that would not be considered part of the designated record set. For example, EHRs contain preliminary results or notes that are in the process of being written. EHRs also contain data that is not PHI, such as audit logs and operational data necessary to manage the coordination of care.

h. Whether EHR should be defined more broadly to include all ePHI in a designated record set, and benefits or drawbacks of doing so.

Per our previous comments, the term "EHR" is usually used in the industry to refer to a system used to capture electronic health information, rather than to refer to a singular record. As described above, we suggest the focus be on a definition of the class of data, rather than on the containing system.

j. Any other effects, burdens, or unintended consequences of the proposed definition of EHR or of including a definition for EHR in the Privacy Rule.

Focusing on the data definition (rather than on the system definition) will have the advantage of not inadvertently excluding any health information technology that should be subject to the same expectations.

r. Whether any federal or state law time limit shorter than 15 calendar days that applies to disclosures of PHI to a third party (e.g., public health agency) should be deemed a “practicable” time limit under the Privacy Rule right of access.

We hear frequent questions from healthcare providers regarding the different timeframes established for the patient right of access, in comparison to other federal programs such as Promoting Interoperability or information blocking compliance. Guidance for providers on the interrelationship of these timeframes would be appreciated.

About the HIMSS EHR Association

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