

May 6, 2021

Dr. Robinsue Frohboese
Acting Director, Office for Civil Rights
U.S. Department of Health & Human Services
200 Independence Avenue, Humphrey Building
Washington, DC 20021

Submitted electronically at: <https://www.Regulations.gov>

Re: Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to Coordinated Care and Individual Engagement (HHSOCR-0945-AA00)

Dear Dr. Frohboese:

Thank you for the opportunity to provide comments on the *HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement*. The Alliance for Nursing Informatics appreciates the review process and the opportunity to comment.

The Alliance for Nursing Informatics (ANI), co-sponsored by AMIA and HIMSS, advances nursing informatics leadership, practice, education, policy, and research through a unified voice of nursing informatics organizations. We transform health and healthcare through nursing informatics and innovation. ANI is a collaboration of organizations representing more than 20,000 nurse informaticists and brings together 25 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and works in collaboration with the more than 4 million nurses in the U. S. in practice today.

We have reviewed the proposed modifications and offer our comments as nursing informatics stakeholders across all care settings. ANI has long advocated for patient-centered health policy and regulations. We strongly support the efforts of the U.S. Department of Health & Human Services (HHS) to modify the HIPAA privacy rule with a focus on engaging and empowering individuals to access and manage their own health data. In the table below, we have identified opportunities for improvement. Our recommendations focus on maximizing individuals' engagement in their care while still protecting the privacy and security of an individual's protected health information (PHI) and address regulatory burdens that may impede the transition to value-based healthcare.

We are available and willing to support and collaborate on further development of this response, as well as future public responses on these important health and healthcare issues.

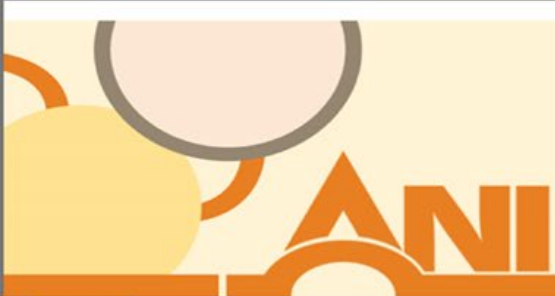
Sincerely,



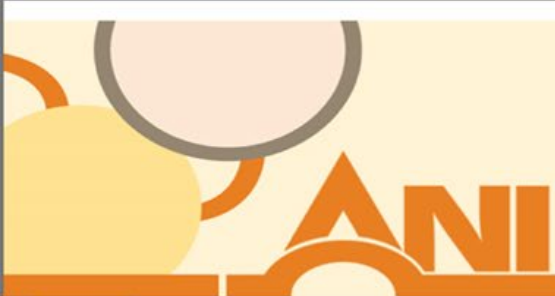
Susan Hull, MSN, RN-BC, NEA-BC, FAMIA
ANI Co-chair



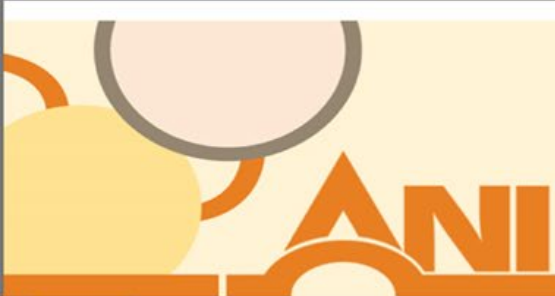
Nancy Beale, MSN, RN-BC
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III.A.1. Adding Definitions for <i>Electronic Health Record</i> or EHR and <i>Personal Health Application</i> 45 CFR 164.501 (FR p. 6455)	
<p>Proposed New Definition: <i>Electronic health record means an electronic record of 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.</i></p> <ul style="list-style-type: none"> • What is a Clinician? OCR proposes to interpret “authorized health care clinicians and staff” to at least include covered health care providers who are able to access, modify, transmit, or otherwise use or disclose PHI in an EHR, and who have direct treatment relationships with individuals; and their workforce members (as workforce is defined at 45 CFR 160.103) who support the provision of such treatment by virtue of their qualifications or job role. • OCR does not propose to include covered health care providers who have indirect treatment relationships with individuals. By definition, providers with indirect treatment relationships deliver health care based on the orders of another health care provider, and they typically provide services, products, or reports to another health care provider (e.g., a provider with a direct treatment relationship with the individual). Accordingly, the direct treatment provider that receives such services, products, or reports would be the entity documenting information in the EHR.160.103) who support the provision of such treatment by virtue of their qualifications or job role. 	<p>ANI is concerned that distinctions between direct and indirect treatment relationships could result in misinterpretation or confusion. We recommend further clarification of the rationale for distinguishing between direct and indirect treatment relationships. ANI advocates for an interprofessional team-based healthcare perspective and suggests that it would be preferable for HIPAA-related protections to apply to individuals generating information related to an individual’s care, regardless of whether their relationship to an identified patient is direct or indirect. For example, nurse care managers may engage directly with patients (e.g., remote patient monitoring) as well as with the interprofessional care team to coordinate ongoing follow-up interventions.</p>
III.A.3. Modify the Implementation Requirements for Requests for Access and Timely Action (FR p. 645)	
<p>The Department believes that entities can provide individuals access to their information within a time limit shorter than 30 days. Therefore, to strengthen the individual’s right of access to their PHI in a designated record set, the Department proposes to modify section 164.524(b)(2)(i) and (ii) of the Privacy Rule to require that access be provided “as soon as practicable,” but in no case later than 15 calendar days after receipt of the request, with the possibility of one 15 calendar-day extension.</p>	<p>Comments</p> <p>ANI supports the recommended changes to make timely access a priority. We recognize smaller and/or under-resourced healthcare settings may encounter challenges in meeting these time limits and suggest that support be provided to such entities to avoid adverse impacts on individuals’ access to their PHI. ANI suggests that certain non-preventable barriers, such as natural disasters, could be included as a cause for an automatic 15 calendar-day extension.</p>

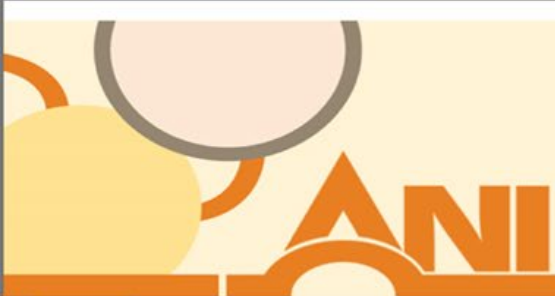


III.A.4. Addressing the Form of Access (FR p. 6461)	Comments
<p>If the individual requests electronic access to PHI that the covered entity maintains electronically, the covered entity must provide the individual with access to the information in the requested electronic form and format, if it is readily producible in that form and format, or if not, in an agreed upon alternative, readable electronic format.</p> <p>The Department seeks comments on related situations: Whether to require a health care provider that has EHR technology that incorporates a secure, standards-based API without extra cost, to implement the API; whether to require a health care provider that could implement such an API at little cost to do so; and how to measure the level of cost that would be considered a reasonable justification for not implementing an API.</p>	<p>Patients request PHI as a method to access and often consolidate their healthcare information. This process needs to be clear, easy, and frictionless for the patients to get their data in a timely way.</p> <p>ANI supports the intention to provide access electronically to the health data in the record but recognizes there is variation in the way healthcare facilities provide access to the EHR, including use of patient portals.</p>
III.A.7. Notices of Access and Authorization Fees (FR p. 6467)	Comments
<p>Specifically, covered entities would be required to post a fee schedule online (if they have a website) and make the fee schedule available to individuals at the point of service, upon an individual's request. The notice must include: (i) All types of access available free of charge and (ii) fee schedule for: (A) Copies provided to individuals under 45 CFR 164.524(a), with respect to all readily producible electronic and non-electronic forms and formats for such copies; (B) copies of PHI in an EHR and directed to third parties designated by the individual under 45 CFR 164.524(d), with respect to all readily producible electronic forms and formats for such copies; and (C) copies of PHI sent to third parties with the individual's valid authorization under 45 CFR 164.508, with respect to all available forms and formats for such copies.</p>	<p>ANI supports transparency of fees in the proposed recommendations. ANI requests clarification on the reasons for differentiating between copies provided directly to an individual (A) versus copies of PHI directed to third parties (B&C). ANI suggests that costs should be the same regardless of the type of copy.</p>
Request for Comment: Section III.A.9 (FR p. 6468)	Comments
<p>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.</p>	
<p>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.</p>	<p>There are instances of professional organizations and health plans creating and maintaining healthcare information data lakes and EHRs. When they do, they should be treated as covered entities under HIPAA.</p>
<p>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.</p> <p><i>Designated record set means: (1) A group of records maintained by or for a covered entity that is: (i) The medical records and billing records about individuals maintained by or for a covered health care provider; (ii) The enrollment, payment, claims adjudication,</i></p>	<p>ANI supports harmonization and alignment of terms and efforts across different regulations, reporting programs, and federal agencies.</p>



<p><i>and case or medical management record systems maintained by or for a health plan; or (iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals. (2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.</i></p>	
<p>d. Whether the proposed definition of EHR includes PHI outside of an electronic designated record set, whether it should, and examples of such PHI.</p>	<p>The proposed definition of EHR should be broad enough to include PHI outside the designated record set. A patient should have the right to see and control any information that meets the definition of patient information.</p>
<p>e. Whether the proposed interpretation of “health care clinicians and staff” as it relates to the proposed EHR definition is appropriate, too broad, or too narrow, and in what respects.</p>	<p>ANI supports the proposed definition of “health care clinicians and staff”</p>
<p>f. Should “health care clinicians and staff” be interpreted to mean all workforce members of a covered health care provider? What are the benefits or adverse consequences of such an interpretation? Does the same interpretation apply regardless of whether the provider has a direct treatment relationship with individuals, and why or why not?</p>	<p>See our above comments on direct/indirect treatment relationships. ANI supports an interprofessional team-based healthcare perspective on workforce interpretations. There may be instances when non-clinician staff of a health care provider need to access PHI as part of care provision, supporting the need for role-based access for all workforce members. To protect patient privacy and confidentiality, we emphasize the importance of current standards for the protection of PHI, including the HIPAA minimum necessary standard. In addition, accountability and oversight are key features to ensure that workforce members are only gaining access as necessary for quality care provision.</p>
<p>g. Are there other health care industry participants that have access to or maintain EHRs that should be explicitly recognized in the definition of EHR or that OCR should consider when establishing such a definition?</p>	<p>Researchers, students, and those that maintain health information systems with or without clinical duties, should be recognized as having access to EHRs and upholding PHI privacy.</p>
<p>h. Whether EHR should be defined more broadly to include all ePHI in a designated record set, and benefits or drawbacks of doing so.</p>	<p>See comments in section c. above.</p>
<p>i. Should the definition of EHR for Privacy Rule purposes be aligned with other Department authorities or programs related to electronic health information? If so, which ones and for what purposes?</p>	<p>ANI supports harmonization and alignment of terms and efforts across federal agencies. When terms have different or subjective definitions, it can lead to confusion and lack of standardization across the industry.</p>

III.B. Reducing Identity Verification Burden for Individuals Exercising the Right of Access (45 CFR 164.514(h)) (FR 6458)



Proposed: Expressly prohibit a covered entity from imposing unreasonable identity verification measures on an individual (or his or her personal representative) exercising a right under the Privacy Rule. 45 CFR 164.514(h)(2)(v)

Clarify within the regulatory text that unreasonable verification measures are those that require an individual to expend unnecessary effort or expense when a less burdensome verification measure is practicable for the particular covered entity.

(v) Exercise of individual rights. A covered entity may not impose unreasonable verification measures on an individual that would impede the individual from exercising a right under this part. An unreasonable measure is one that causes an individual to expend unnecessary effort or resources when a less burdensome verification measure is practicable for the covered entity. Practicability considerations include a covered entity's technical capabilities, its obligations to protect the privacy of protected health information under § 164.530(c), the security of electronic protected health information under § 164.306, and the costs of implementing measures that are more convenient for individuals. Examples of unreasonable measures include requiring an individual to provide proof of identity in person when a method for remote verification is practicable for the covered entity and more convenient for the individual, or requiring an individual to obtain notarization of the individual's signature on a written request to exercise the individual right.

The Department proposes to clarify that a covered entity that implements a requirement for individuals to submit a request for access in writing would not be permitted to do so in a way that imposes unreasonable burdens on individuals. The proposed change to prohibit a covered entity from implementing unreasonable identity verification requirements complements the first proposal to ensure that an individual is afforded as much flexibility as reasonable when accessing his or her own records.

- Agree with the example given - these have been shown to be a barrier during the pandemic: individual to obtain notarization of the individual's signature, or accepting individuals' written requests only in paper form, only in person at the covered entity's facility, or only through the covered entity's online portal.

- There should not be an 'only' requirement - not 'only' hardcopy or 'only' an online portal. As demonstrated by the pandemic, reliance on library access to a computer is not feasible when libraries are closed. Suggest providing two alternatives such as an in-person and an electronic alternative to decrease this barrier.

- Access to a notary incurs an expense as well as access issues, so we agree that is a barrier. Organizations should create options other than in-person such as a video chat and incorporate identity verification into an on-line process in addition to in-person.

- ANI agrees with not making authentication overly burdensome. Requiring authentication and authorization going through the portal is not scalable and not equitable. ANI recommends support of the Trust framework.