Pharmacy Health Information Technology Collaborative

Via Electronic Submission to: https://www.regulations.gov
(Docket ID: HHS-OCR-0945-AA00)

May 6, 2021

Ms. Robinsue Frohboese
Acting Director and Principal Deputy
Office for Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

Re: [NPRM: RIN 0945-AA00] Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement

Dear Ms. Frohboese:

On behalf of the membership of the Pharmacy Health Information Technology (PHIT) Collaborative, we are pleased to submit comments regarding the proposed modifications to the HIPAA Privacy Rule.

PHIT has been involved with the federal agencies in developing the national health information technology (HIT) framework since 2010. Pharmacists are users of health IT and provide essential patient-centered services, which may utilize patient health information. Ensuring that patient health information is secure and protected, especially personal health information (PHI) and electronic health records (EHR), is a priority of pharmacists in all practice settings.

The following comments pertain to the proposed modifications to the HIPAA privacy rule:

A. Individual Right of Access

1. Adding Definitions for Electronic Health Record or EHR and Personal Health Application (pages 41-48)

PHIT supports adding the proposed EHR definition to 45 CFR 164.501 to expand and clarify the HITECH Act EHR definition. PHIT especially appreciates and thanks the department for clarifying who are health care professionals and adding pharmacists as health care professionals in the EHR definition. Additionally, PHIT supports the department's proposed

interpretation of "'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 we understand, this includes electronic records consulted by any covered health care provider or workforce member who has a direct treatment relationship with individuals.

2. Strengthening the Access Right to Inspect and Obtain Copies of PHI (pages 49-52)

PHIT supports allowing covered entities to provide copies of PHI in lieu of in-person inspection of PHI, when necessary, to protect the health and safety of individuals or others, such as during a pandemic.

PHIT does not believe a covered health care provider should be required to allow an individual to record their PHI via video or cellphone. Allowing an individual to do this should be an option and at the discretion of the covered health care provider, not a requirement. Pharmacists would have difficulty complying with such a requirement. Records maintained by a pharmacist are electronic and are viewed on a computer monitor. The monitor is accessible only by the pharmacist, not the individual. Capturing PHI by video or cellphone would entail recording what is displayed on the monitor. To comply with this proposed requirement would add expense for setting up a private area with a dedicated computer and monitor, provided the pharmacy has available space, and could disrupt workflow – two unintended consequences. Generally, if an individual asks to see certain records, the pharmacist would provide the individual with an electronic or printed copy, making the recording of PHI unnecessary.

If the department plans to move forward with this provision, then exemptions need to be included to cover certain circumstances, such as those noted above.

It also appears that this proposed provision may not be fully in alignment with the Center for Medicare and Medicaid Services' (CMS) Interoperability and Patient Access Final Rule and the Office of the National Coordinator's (ONC) Cures Act Final Rule provisions to provide patients electronic access to their electronic health information (EHI). The HIPAA Privacy Rule and proposed modifications need to be aligned with these current rules.

5. Addressing the Individual Access Right to Direct Copies of PHI to Third Parties (pages 67-77)

PHIT supports the proposed provision in subsection (d) of 45 CFR 164.524 that an individual's request to direct copies of PHI from a covered health care provider to a third party designated by the individual will be limited to only electronic copies of PHI in an EHR. PHIT would support allowing an oral request, as an additional option, provided the oral request is "clear, conspicuous, and specific," and the individual is verified. The proposal does not address

verifying the individual (or the individual's representative) making an oral request nor documenting the request. Electronic requests and other written requests have verification and documentation methods built in. Lastly, PHIT supports allowing a covered health care provider to facilitate an individual's request to direct an electronic copy of PHI in an EHR to one or more covered health care providers, as well as obtain a copy of PHI in an EHR from one or more covered health care providers.

9. Requests for Comments (pages 93-101)

e. Whether the proposed interpretations 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.

PHIT believes the interpretation of health care clinicians and staff is appropriate and includes appropriate examples.

f. Should "health care clinicians and staff" be interpreted to mean all workforce members of a covered health care provider, et al.

PHIT suggests that workforce members should be interpreted to mean those authorized to access and maintain PHI and EHRs for a covered health care provider, which is not necessarily all workforce members.

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?

PHIT believes the EHR definition for the purpose of this rule needs to be aligned particularly with the activities and programs regulated by ONC and CMS. The government has spent billions of dollars over the years to get medical and health professions to adopt EHR[1], and yet, inconsistencies in various rules and interpretations by the agencies and departments involved are contributing to EHRs not living up to their potential. Consistency in all aspects, especially with definitions, is critical to the success of EHRs.

t. Any benefits or drawbacks of the proposal to require a covered entity to act on an oral access request to either direct an electronic copy of PHI in an EHR to a third party or direct a covered entity to submit such a request, provided the oral communication is clear, conspicuous, and specific.

An oral access request is beneficial for those who may not have access to electronic communication or internet-based methods. Although data show a steady increase in mobile

[1] Andrew Muchmore, "Government rules led electronic records astray. It's time to reimagine them." STAT Health Tech. March 27, 2020. https://www.statnews.com/2020/03/27/government-rules-led-electronic-health-records-astray-its-time-to-reimagine-them/

phone and other electronic devices ownership over time, there is still a large portion of the U.S. population that does not own such devices. According to the Pew Research Center, "81% of Americans own smartphones, and nearly three-quarters of U.S. adults now own desktop or laptop computers, while roughly half now own tablet computers."[2] As more people become reliant on smartphones and access health care apps, that data show just 53% of those 65 and older own a smartphone.[3]

A potential downside for a covered entity to act on an oral access request is the additional time it may take to verify the individual and document the request. Electronic systems have processes built in that verify and document the individual making the request as part of the system's security protocols; it's not the covered entity performing the verification and documentation.

B. Reducing Identity Verification Burden for Individuals Exercising the Right of Access (pages 102-109); Request for Comments

b. What verification standard should apply when a covered health care provider or health plan submits an individual's access request to another covered health care provider or health plan? Specifically, should the covered entity that holds the requested PHI be required to verify the identify and authority of the covered entity that submitted the request, but be permitted to rely on the requesting entity's verification of the identity of the individual (or personal representative)?

To ensure security and protect privacy, PHIT believes verifications of identity and authority should be done by a covered health care provider before sharing any individual's PHI with another covered health care provider or health plan. This could be done easily through the electronic systems used by covered health care providers and health plans. Such systems, ideally, should be certified EHR technology (CEHRT) through the ONC HIT and CMS Certification Programs and adhere to those standards.

D. Creating an Exception to the Minimum Necessary Standard for Disclosures for Individual-level Care Coordination and Case Management (pages 112-121)

PHIT supports the proposal for adding an "express exception" to the minimum necessary standard for disclosures that "would relieve covered entities from the requirement to make determinations about the minimum information necessary when the request is from, or the disclosure is made to, a covered health care provider or health plan to support individual-level care coordination and case management activities."

[2] Mobile Fact Sheet. Pew Research Center, Internet & Technology. June 12, 2019. https://www.pewresearch.org/internet/fact-sheet/mobile/

[3] Ibid.

G. Eliminating Notice of Privacy Practices Requirements Related to Obtaining Written Acknowledgment of Receipt, Establishing an Individual Right to Discuss the NPP with a Designated Person, Modifying the NPP Content Requirements, and Adding an Optional Element (pages 158-166)

PHIT supports removing the requirements for a covered health care provider with a direct treatment relationship to an individual to obtain a written acknowledgment of receipt of the provider's NPP (notice of privacy practices) if unable to obtain such and replace with an individual's right to discuss the NPP with a person designated by the covered entity.

H. Permitting Disclosure for Telecommunications Relay Services [TRS] for People Who are Deaf, Hard of Hearing, or Deaf-Blind, or Who have a Speech Disability (pages 166-170)

PHIT supports expressly permitting covered entities (and business associates) to disclose PHI to TRS communications assistants "relating to any covered functions performed by, for, or on behalf of covered entities and clarify for covered entities that a business associate agreement is not needed with a TRS communications assistant." This change will be beneficial to pharmacists, staff, and their patients who may be hearing impaired, deaf-blind, or have a speech disability and communicate using TRS for care coordination and other purposes.

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The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. The Collaborative's membership is composed of the key national pharmacy associations involved in health information technology (HIT), the National Council for Prescription Drug Programs, and 13 associate members encompassing e-prescribing, health information networks, transaction processing networks, pharmacy companies, system vendors, pharmaceutical manufacturers, and other organizations that support pharmacists' services.

As the leading authority in pharmacy health information technology, the Pharmacy HIT Collaborative's vision and mission are to ensure the U.S. health IT infrastructure better enables pharmacists to optimize person-centered care. Supporting and advancing the use, usability, and interoperability of health IT by pharmacists for person-centered care, the Collaborative identifies and voices the health IT needs of pharmacists; promotes awareness of functionality and pharmacists' use of health IT; provides resources, guidance, and support for the adoption and implementation of standards-driven health IT; and guides health IT standards development to address pharmacists' needs. For additional information, visit www.pharmacyhit.org.

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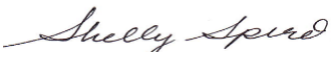
On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the proposed modifications to the HIPAA privacy rule.

For more information, contact Shelly Spiro, executive director, Pharmacy HIT Collaborative, at shelly@pharmacyhit.org.

Respectfully submitted,



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