Pharmacy Health Information Technology Collaborative

Via Electronic Submission to: http://www.regulations.gov
Docket ID Number: HHS-OCR-0954-AA00

February 12, 2019

U.S. Department of Health
and Human Services
Office for Civil Rights
Attn: RFI, RIN 0945-AA00
Hubert H. Humphrey Building, Room 509F
200 Independence Ave., SW
Washington, DC 20201

Re: RFI on Modifying HIPAA Rules to Improve Coordinated Care

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we appreciate the opportunity to submit comments for the *RFI on Modifying HIPAA Rules to Improve Coordinated Care.*

Pharmacists, who are covered entities under the Health Insurance Portability and Accessibility Act (HIPAA), provide essential pharmacy and health-related services to patients. Additionally, pharmacists use health IT, including electronic health records (EHRs), while preserving the security of protected health information (PHI). The Collaborative supports the use of these systems, which are important to pharmacists in working with other health care providers to provide needed medications and transmit patient information related to overall patient care, transitions of care, immunization (historical and administered), immunization registry reporting, medication lists, medication allergies, allergy reactions, patient problem lists, smoking status, reporting to public health agencies, clinical decision support services/knowledge artifacts, drug formulary checking, and electronic prescribing.

The Collaborative has been involved with the federal agencies, including the Office of the National Coordinator (ONC) and the Centers for Medicaid and Medicare Services (CMS), in developing the national health information technology (HIT) framework and standards since 2010.

The following are our comments that focus primarily on the existing EHR systems section of the *RFI on Modifying HIPAA Rules to Improve Coordinated Care.*

30) In what scenarios would a business associate make a disclosure of PHI for TPO through an EHR?

As covered entities under HIPAA and users of EHR, pharmacists would only disclose information that is required for TPO (treatment, payment, and health care operations), just as other health care providers do.

32a) Is the system able to distinguish between "uses" and "disclosures" as those terms are defined under Privacy Rule at 45 CFR 160.103?

The Collaborative supports systems that can distinguish between uses and disclosures. Whether a system could distinguish between the two is dependent on the technology that is used in an EHR system. The Collaborative encourages the adoption of pharmacy systems that can do this.

32f) To what extent do covered entities maintain a single, centralized EHR system versus a decentralized system (e.g., different departments maintain different EHR systems, and an accounting of disclosures for TPO would need to be tracked for each system)?

As mentioned previously, this depends on the technology used and the arrangements and policies/procedures between the departments and business associate agreements that protect information and allow sharing for coordinated care.

32g) Do existing EHR systems automatically generate an accounting of disclosures under the current Privacy Rule (i.e., does the system account for disclosures other than to carry out TPO)?

Some pharmacy EHR systems automatically generate an accounting of disclosures, while for other systems, it is done manually (depends on the pharmacy system and technology that is used). The Collaborative supports the use of both ways.

37) What data elements should be provided in an accounting of TPO disclosures and why? How important is it to individuals to know the specific purpose of a disclosure – i.e., would it be sufficient to describe the purpose generally (e.g., "for treatment," "for payment," or "for health care operations purposes"), or is more detail necessary for the accounting to be of value? To what extent are individuals familiar with the range of activities that constitute "health care operations?"

As covered entities under HIPAA and health care providers, pharmacists take responsibility to disclose information upon request. It is a burden to give specific details of the TPO for an individual's general request, unless there is an inquiry (complaint).

Providing a more general-purpose element (e.g., for treatment; for payment) may be sufficient for most individual requests. The Collaborative does not believe most individuals are familiar with the range of activities that constitute health care operations.

39) If covered entities are unable to modify existing systems or process to generate a full accounting of disclosures for TPO (e.g., because modifications would be prohibitively costly), should OCR instead require covered entities to conduct and document a diligent investigation into disclosures of PHI upon receiving an individual's request for an accounting of disclosures for TPO?

If the OCR is considering moving in this direction, the Collaborative believes this should be confined to complaints, for the time being, and applicable to those complaints in which an individual has been harmed. At the moment, this is not part of standard operating procedures. Until that time, organizations, particularly small organizations, should not be forced to conduct investigations for all accounting disclosure requests received. When there are complaints, then it would make sense that covered entities conduct and document a diligent investigation into disclosures of PHI. When there isn't a complaint, then it shouldn't be required.

40) If OCR requires or permits covered entities to conduct an investigation into TPO disclosures in lieu of providing a standard accounting of such disclosures, what information should the entities be required to report to the individual about the findings of the investigation? For example, should OCR require covered entities to provide individuals with the names of the persons who received TPO disclosures and the purpose of the disclosures?

The Collaborative believes that only information pertinent to resolving a complaint should be reported to the individual about the findings of the investigation.

41) The HITECH Act, section 13405(c) only requires the accounting of disclosures for the TPO to include disclosures through an EHR. In its rulemaking, should OCR likewise limit the right to obtain an accounting of disclosures for TPO to PHI maintained in, or disclosed through an EHR?

The Collaborative recommends that OCR follow the HITECH Act in this regard.

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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 of Prescription Drug Programs, and nine 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-center 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 *RFI on Modifying HIPAA Rules to Improve Coordinated Care.*

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

Respectfully submitted,

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