



# Pharmacy e-Health Information Technology Collaborative

VIA Electronic Submission to <http://www.regulations.gov>

August 1, 2011

Kathleen Sebelius  
Secretary  
Department of Health and Human Services  
Office of Civil Rights  
Attn: HIPAA Privacy Rule Accounting for Disclosures, RIN 0991-AB62  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Re: 45 CFR Part 164: HIPAA Privacy Rule Accounting of Disclosures under the  
Health Information Technology for Economic and Clinical Health Act; Notice of  
Proposed Rulemaking

Dear Secretary Sebelius:

On behalf of the membership of the Pharmacy e-Health Information Technology Collaborative (Collaborative), we are pleased to submit comments in response to the proposed rule, *HIPAA Privacy Rule Accounting of Disclosures under the Health Information Technology for Economic and Clinical Act (HITECH); Notice of Proposed Rulemaking (NPRM) (76 Fed Reg 31426-449)* published in the *Federal Register* on May 31, 2011. The Collaborative generally supports the goals of the Department of Health and Human Services (HHS) to allow individuals to receive information regarding uses and disclosures of protected health information to assist providing greater transparency regarding the uses and disclosures of information. However, the Collaborative is concerned that the NPRM is an overly burdensome requirement for covered entities. Specifically, the time and resources investment required to implement systems to track and monitor uses and disclosures of PHI, including for treatment, payment, and operations and to closely monitor uses and disclosures by business associates is costly relative to benefit. The NPRM recognizes that few individuals have requested access to information under the current HIPAA disclosure requirements. The HITECH proposed rule requiring reporting of uses and disclosures for treatment, payment, and operations adds an additional layer of administrative burdens for covered entities and business associates. Given this situation, the Collaborative believes HHS should carefully review comments and use its administrative discretion to support less burdensome provisions; delay implementation; and consider improvements to provisions in the existing privacy, security, and breach rules as an alternative to some of the proposed provisions in the NPRM. Given that the proposed rule is overly burdensome to covered entities

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and business associates, the Collaborative suggests that HHS withdraw the rule as proposed and work with stakeholders to develop a rule that is more consistent with the provisions implemented under HITECH. As HHS develops its revisions, it should require that access reports only be provided through an electronic health record pursuant to reflect the HITECH Act.<sup>1</sup>

Formed in the fall of 2010, the Collaborative's focus is to assure the meaningful use (MU) of standardized electronic health records (EHRs) support safe, efficient, and effective medication use, continuity of care, and provides access to the patient-care services of pharmacists with other members of the interdisciplinary patient-care team.

The Collaborative seeks to ensure that pharmacist-provided patient care services in all practice settings are represented in the MU of EHRs. The Collaborative's founding organizations represent pharmacists in all patient care settings and other facets of pharmacy, including pharmacy education and pharmacy education accreditation. The Collaborative's Associate Members represent e-prescribing networks, a standards development organization, transaction processing networks, pharmacy companies and other organizations that support pharmacists providing patient care services. The Collaborative was founded by nine pharmacy professional associations representing over 250,000 members and includes three associate members from other pharmacy related organizations. For additional information, visit [www.pharmacyhit.org](http://www.pharmacyhit.org)

The Collaborative is concerned that individuals seeking disclosure reports will receive very little benefit from the information relative to the development and support costs. In the NPRM, HHS provides an example of an access report that is "formatted to be understandable to an individual"<sup>2</sup>. The example includes the date, time, the name of the individual who accessed the information, and the action taken.<sup>3</sup> While this information seems to provide an accurate representation of an activity, it provides very little useful information for an individual to determine whether the information was used improperly or the purpose of such action. The NPRM also suggests that some PHI may reside outside of designated record sets and thus be excluded from the accounting for disclosure requirement, but are covered by the Privacy, Security, and Breach Notification rules. If, as HHS suggests, the primary purpose of the accounting for disclosures rule is to allow individuals to receive information that is of most interest to them in regard to determinations regarding entities that access their PHI,<sup>4</sup> the listing of general information as described above may not aid an individual in determining whether further action is necessary to protect their PHI. It would be more appropriate for HHS to consider improvements to the breach notification interim rule and privacy and security rules currently under review at HHS to provide meaningful and useful information for consumers regardless of whether the information is contained in a designated record set or outside of a designated record set. The accounting for disclosure provisions in addition to the privacy, security, and breach notification requirements create confusion for individuals and also create

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<sup>1</sup> HITECH Act §13405(c)(2).

<sup>2</sup> 76 Fed. Reg. 31440.

<sup>3</sup> *Ibid.*

<sup>4</sup> 76 Fed. Reg. 31429.

unnecessary burdens for covered entities and business associates to create systems to track and monitor the use of information.

HHS acknowledges in the NPRM that it cannot estimate the costs associated with implementing systems to provide an accounting for disclosures and encourages commenters to provide such information.<sup>5</sup> The Collaborative encourages HHS to carefully review comments regarding cost estimates; compare the true impact of these provisions and determine whether the benefits outweigh the costs and burdens; and make changes in the final rule and harmonize these changes with the privacy, security and breach rules. Specifically, the Collaborative offers the following suggestions:

- Eliminate the need for access reports containing information related to “uses” of information internally by the covered entity and only require disclosures to external entities.
- HHS should use its statutory authority to extend the compliance dates to 2013 for entities that acquired EHRs after January 1, 2009 and to 2016 for entities that acquired EHRs prior to January 1, 2009. The extension will provide the necessary time to implement any statutory changes and to allow standards development for accounting disclosures through health information exchanges.

Assuming that the proposed requirements are maintained, the Collaborative supports the implementation proposed 3-year timeframe for recordkeeping of access logs and reports and disclosures rather than the 6-year timeframe imposed by HIPAA.<sup>6</sup> The Collaborative also supports maintaining the 60-day timeframe for responding to requests for information rather than imposing a 30-day timeframe<sup>7</sup>. The expanded timeframe allows covered entities and business associates to gather and disseminate information. Finally, the Collaborative agrees that information subject to the breach notification rule should be excluded from the accounting for disclosures requirement.

On behalf of the Pharmacy e-HIT Collaborative, thank you again for the opportunity to comment on the accounting for disclosures NPRM. The Collaborative will continue to work with HHS to ensure privacy and security standards strike an appropriate balance to ensure protection of PHI and administrative efficiencies that do not unfairly burden health care providers. For more information, contact Shelly Spiro, Director, Pharmacy e-HIT Collaborative at [shelly@pharmacyhit.org](mailto:shelly@pharmacyhit.org).

Respectfully submitted,



Shelly Spiro Director, Collaborative

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<sup>5</sup> 76 Fed. Reg. 31444.

<sup>6</sup> 76 Fed. Reg. 31430 & 31447-8 referencing 45 CFR §164.528 (b)(1) and (4).

<sup>7</sup> 76 Fed. Reg. 31447-8 referencing 45 CFR §164.528 (a)(3).

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