May 14, 2010

Georgina Verdugo
Director, Office for Civil Rights
U.S. Department of Health and Human Services (HHS)
Attention: HITECH Accounting of Disclosures
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

Dear Director Verdugo:

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents over 94,700 physicians and medical students nationwide. Specifically, I am writing to share our comments on questions raised in the request for information (RFI) on "HIPAA Privacy Rule Accounting of Disclosures under the Health Information Technology for Economic and Clinical Health (HITECH) Act," as published in the *Federal Register* on May 3, 2010. We will focus on those questions that relate most directly to the administrative burden that this places on covered entities, such as family physicians and their practices.

As noted in the RFI, section 13405(c) of the HITECH Act requires HHS to revise the HIPAA Privacy Rule to require covered entities to account for disclosures of protected health information to carry out treatment, payment, and health care operations if such disclosures are through an electronic health record. As regards that requirement, we would like to address the following questions raised in the RFI:

If you are a covered entity, how do you make it clear to individuals their rights to receive an accounting of disclosures? How many requests for an accounting have you received from individuals?

> It is our understanding that most family medicine practices post a notice of these rights in the office and provide the information in their HIPAA Privacy notices. We do not have any data on the number of requests that the typical family physician receives. We expect that the number is infrequent and variable and probably dependent on local circumstances. For example, when there is a news report of a breach in HIPAA privacy in the community, we expect that patients are more likely to generate requests for an accounting of disclosures from their own family physician's office.

With respect to treatment, payment and health care operations disclosures, 45 CFR 170.210(e) currently provides the standard that an electronic health record system record the date, time, patient identification, user identification, and a description of the disclosure. In response to its interm final rule, the Office of the National Coordinator for Health Information Technology received comments on this standard and the corresponding certification criteria suggestion that the standard include to whom a disclosure was made (i.e. recipient) and the reason or purpose for the disclosure. Should an accounting for treatment, payment,

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and health operations disclosures include these or other elements and, if so why? How important is it to the individual know the specific purpose of the disclosure-i.e., would it be sufficient to describe the purpose generally (e.g. for "for treatment," "for payment," "for health care operations"), or is more detail necessary for the accounting to be of value? To what extent are individuals familiar with the different activities that may constitute "healthcare operations?" On what do you base this assessment?

From our perspective, if an electronic health record (EHR) system can record the date, time, patient identification, user identification, and a description of the disclosure, along with recipient identification and general reason for disclosure (i.e., for treatment, payment, or health care operations), that should be sufficient. As noted above, we expect that requests for an accounting of disclosures are infrequent, and this information captured by the EHR should satisfy most patients. Further, the references "for treatment" and "for payment" should be self-explanatory, especially when paired with the recipient's identification (e.g., another health care provider or a third-party payer). We expect that most patients do not know what is involved in "healthcare operations." However, we also expect that most patients do not care unless there is a problem. Thus, in most cases, it appears that just leaving it as "healthcare operations" would suffice.

For existing electronic health record systems:

(a) Is the system able to distinguish between "users" and "disclosures" as those terms are defined under the HIPAA Privacy Rule? Note that the term "disclosures" includes the sharing of information between a hospital and physicians who are on the hospital's medical staff but who are not members of its workforce.

(b) If the system is limited to only recording access to information without regard to whether it is a use or disclosure, such as certain audit logs, what information is recorded? How long is such information retained? What would be the burden to retain the information for three years?

(c) If the system is able to distinguish between uses and disclosures of information, what data elements are automatically collected by the system for disclosures (i.e., collected without requiring any additional manual input by the person making the disclosure)? What information, if any, is manually entered by the person making the disclosure?

(d) If the system is able to distinguish between uses and disclosures of information, does it record a description of disclosures in a standardized manner (for example, des the system offer or require a user to select from a limites list of types of disclosures)? If yes, is such a feature utilized and what are the benefits and drawbacks?

(e) Is there a single, centralized electronic health record system? Or is it a decentralized system (e.g., different departments maintain different electronic health record systems and an accounting for of disclosures for treatment, payment, and health care operations would need to be tracked for each system)?

(f) Does the system automatically generate an accounting for the disclosures under HIPAA Privacy Rule (i.e., does the system account for disclosures other than to carry out treatment, payment and health care operations)?

i. If yes, what would be the additional burden to also account for disclosures to carry out treatment, payment, and health are operations? Would there be additional hardware requirements (e.g., to store such accounting information)? Would such an accounting feature impact system performance?

ii. If not, is there a different system for accounting disclosures, and does it interface with the electronic record system?

Issues around “use” and “disclosure” will be particularly complex and represent a paradigm shift in access to electronic protected health information(ePHI). As we continue to focus on improving care coordination and collaborative approaches to care, which necessitate increased data sharing including ePHI, the amount of “audit” data will substantially outweigh the amount of clinical data in any given EHR and across the healthcare system. We must remain mindful of the intent of the disclosure audit process and remain open to opportunities to preserve the intent but abstract the complexity into manageable and meaningful implementations.

The HITECH Act provides that a covered entity that has acquired an electronic record after January 1, 2009 must comply with the new accounting requirements beginning January 1, 2011 (or anytime after that date when it acquires an electronic health record), unless we extend this compliance deadline to no later than 2013. Will covered entities be able to begin accounting for disclosures through an electronic health record to carry out treatment, payment, and health care operations by January 1, 2011? If not, how much time would it take vendors of electronic health records to design and implement such a feature? Once such a feature is available, how much time would it take for a covered entity to install an updated electronic health record system with this feature?

If a covered entity has fully implemented an EHR that already includes the capability to report the required disclosure accounting elements, then a compliance deadline of January 1, 2011, is probably reasonable. However, covered entities that are in the process of implementing an EHR would benefit from an extension of the compliance date to January 1, 2013. Successful EHR implementation can take a year or longer, so those who are in the process of implementing an EHR now may not be ready to take advantage of the HIPAA disclosure accounting feature(s) by January 1, 2011, especially if they are appropriately focusing on the clinical aspects of the EHR first. Therefore, we would strongly encourage HHS to extend the deadline for compliance to January 1, 2013.

What is the feasibility of an electronic health record module that is exclusively dedicated to accounting for disclosures (both disclosures that must be tracked for the purposes of accounting under the current HIPAA Privacy Rule and disclosures to carry out treatment, payment, and health care operations)? Would such a module work with covered entities that maintain decentralized electronic health record systems?

Such a module would likely take the form of a messaging gateway that could capture a set of defined metadata directly from the disclosure message. This gateway could be installed at the boundary of the covered entity (which may be extended by business associate agreements), whether that was within a single practice, the central billing office of a large system, or the data center of an application service provider. This messaging gateway could also capture metadata from inbound messages containing ePHI, with appropriate standardization of the operational specifications. A significant complication arises in documenting the exact ePHI that was disclosed in a legitimate transaction. We presume that such an accounting is beyond the scope of the HITECH modifications to the HIPAA Privacy Rule.

Thank you for this opportunity to comment on this matter. If you or your staff have any questions or if we may be of further assistance in this regard, please contact Ms. Gail Jones at the AAFP.

Sincerely,

Ted D. Epperly, M.D.
Board Chair

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