

August 1, 2011

Ms. Georgina Verdugo
Director
Office for Civil Rights
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

Attention: HIPAA Privacy Rule Accounting of Disclosures (RIN 0991-AB62); Notice of Proposed Rulemaking, 76 Fed. Reg. 31426 (May 31, 2011).

Dear Ms. Verdugo:

On behalf of the Nebraska Hospital Association's (NHA) 87 member hospitals and the 43,000 individuals they employ, the NHA thanks you for the opportunity to comment on the Department of Health and Human Services' (HHS) Office for Civil Rights' (OCR) May 31 Notice of Proposed Rulemaking related to the HIPAA Privacy Rule Accounting of Disclosures under the *Health Information Technology for Economic and Clinical Health Act* (HITECH) published in the *Federal Register*. We believe that the proposed rule, as drafted, does not appropriately balance the relevant privacy interests of individuals with the burdens on a covered entity, especially the health care facilities, to comply with the rule's obligations to provide an accounting of disclosures and an access report.

The proposal is based on a fundamental misunderstanding of the value to individuals of receiving the particular information that the proposed rule would require covered entities to provide in the revised accounting of disclosures and the entirely new access reports, and a significant misjudgment about the capabilities of technologies available to and used by covered entities to produce relevant information that they must report. As a result, we ask that OCR radically alter its proposed approach to ensure that any final regulatory requirements appropriately fulfill the needs of patients who seek to understand how their protected health information (PHI) is used and disclosed while simultaneously ensuring that covered entities are technically capable of providing such information without incurring unreasonable burdens to do so.

We agree that some of the proposed changes to the accounting of disclosure requirement could improve the value of the information provided to individuals while helping to reduce covered entities' burdens in providing the information. Specifically, we generally concur with the following proposed changes:

- Excluding from the accounting disclosures not permitted by the HIPAA privacy rule when the covered entity already has informed the individual of the impermissible disclosure in a required breach notice letter provided in accordance with current federal breach notification requirements.
- Excluding from the accounting a disclosure to report child abuse or neglect.

- Excluding from the accounting disclosures that are “required by law,” including any disclosures for a purpose that would otherwise be subject to the accounting, *unless* that particular disclosure is for judicial and administrative proceedings or for law enforcement purposes.

We also support the continued exclusion from the accounting obligation, disclosures:

- To individuals of their own PHI.
- Incident to an otherwise permitted or required disclosure.
- Under authorization.
- For the facility directory or to persons involved in the individual’s care or other notification purposes.
- For national security or intelligence purposes.
- To correctional institutions or in law enforcement custodial situations.
- As part of a limited data set.
- Occurring prior to the compliance date for the covered entity.

We also support the agency’s additional exemption of certain categories of disclosures that currently are subject to the accounting obligation for which, in the preamble to the proposed rule, the agency recognizes should be excluded, and specifically articulates a sound rationale for doing so. Specifically, we support the exemption of disclosures:

- Related to reports of adult abuse, neglect or domestic violence;
- For research, including research where an institutional review board (IRB) or privacy board has waived the requirement to obtain individual authorization for the disclosure;
- For health care oversight activities;
- About decedents to coroners, medical examiners and funeral directors; and
- About decedents for cadaveric organ, eye or tissue donation.

All of the exclusions identified previously preserve the value of the accounting for individuals while limiting the burdens to covered entities and should be included in the final rule.

Even if the revised requirement does not increase the frequency of requests to covered entities, the workload to ascertain and include in the accounting all appropriate disclosures will significantly increase because, under the revised provision, covered entities would be required to include directly in the accounting disclosures made by all business associates. The NHA serves as a business associate to our member hospitals for data aggregation purposes. Consequently, we are very concerned that OCR’s proposal to shorten the time period for covered entities to respond to an individual request from 60 days to 30 days only adds to the burdens covered entities face in complying with the accounting requirement without a significant enhancement of the privacy rights of individuals. We believe that the OCR’s proposal to shorten the time period should be rejected and the current rule’s timeliness requirement should be maintained.

In addition, we believe that OCR could reduce further the burdens on covered entities without lessening the value of the accounting to individuals by clearly restricting the accounting to disclosures of PHI contained in the covered entity’s *official* designated record set and

specifically excluding copies of such information – whether exact or partial copies – received and maintained by business associates in the course of their activities on behalf of the covered entity, especially when such copies are not used to make decisions about the individual, as the definition of definition of designated record set clearly requires.

We also believe that OCR should reject in its entirety the proposal to establish an individual right to request and receive from covered entities an access report that identifies who has electronically accessed the individual’s PHI. To comply with specific obligations for providing an access report, hospitals would need, for example, to disclose the identity of employees who are acting in perfectly appropriate ways – doing exactly what they are supposed to be doing – to any patient who makes a request. It is difficult to understand exactly what privacy benefit to patients supplying employees’ names in these circumstances serves. Patients would be unlikely to know anyone by name who is not a member of the direct patient care staff involved in their treatment and receiving a report indicating that someone you do not immediately recall or never knew accessed your information could only serve to raise unnecessarily the patient’s anxiety when there is no other detail about that person’s function and reasons for looking at and using the information. It necessitates that the patient seek additional information directly from the hospital to learn that this was a necessary and appropriate access that routinely occurs in the ordinary course of delivering, paying for and improving health care. In some circumstances, disclosing the identity of employees could raise potential employee safety concerns.

Further, OCR assumes that producing an access report is merely a byproduct of having the technical capability within an electronic information system to create an audit log and print or display the results of that log. But as OCR acknowledges, even a certified electronic health record (EHR) system meeting the requirements for meaningful use may not include relevant audit trail capabilities. A hospital’s EHR system actually consists of many separate systems (e.g., radiology, lab, systems for clinical care in the hospital setting that often differ from the systems for clinical care in clinics and home care settings, patient admitting, patient billing). But the proposed rule’s requirements would extend beyond the hospital’s EHR system to require reporting of accesses of *any* electronic systems containing a designated record set that the covered entity or its business associates maintain.

Audit capability generally is not included and supported by information system vendors because there is nothing that compels its inclusion. Payment of significant additional fees could be required to obtain audit capability for a system. Even if included, audit capabilities are inconsistent across systems and may not be capable of capturing and storing the significant amount of relevant data needed to produce the complete detailed access report as required under the proposal.

Importantly, for any systems that are not already capable of generating an audit trail that produces the necessary information for the required access report, it will be difficult to account for historical accesses during the three years preceding the effective date of any final rule requirements, as OCR’s proposal would require.

Further, we believe that OCR's proposal ignores some real burdens to covered entities of processing audit trail information into a form that is readable and understandable by the patient. It is not just the costs of storing of the audit trail data that are an important consideration in evaluating the burden to a covered entity. The processing time for an information system to generate audit trail information is equally important in determinations of burden. Also critical to the assessment is that no electronic systems, not even certified EHR systems, currently have the technical capability to generate an access report that is meaningful to and understandable by the patient and that can be immediately handed over.

The current HIPAA requirements and practices already ensure that patients are getting the information that they feel they need and value most. To the extent that individuals in fact want to know if someone has been reviewing their records inappropriately, we encourage HHS to evaluate an approach specifically tailored to address that precise concern rather than imposing a process that overwhelms both the individual and the covered entity.

If you have any questions, please feel free to contact me at kconway@nhanet.org or 402-742-8150.

Sincerely,



Kevin Conway
Vice President, Health Information