May 18, 2010

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:  HITECH Accounting of Disclosures

Dear Ms. Verdugo:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to respond to the request for information (RFI) from the Department of Health and Human Services’ Office for Civil Rights (OCR) related to new accounting of disclosures requirements. The Health Information Technology and Clinical Health Act (HITECH) requires OCR to revise the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule to require that hospitals and other covered entities provide to patients, upon their request, an accounting of disclosures of protected health information to carry out treatment, payment and health care operations if the disclosures are through an electronic health record (EHR). We urge the department to take advantage of the flexibility provided in the statute to delay the effective date of the requirement. Specifically, the department should establish, as permitted by HITECH, an effective date of:

- 2016 in the case of a covered entity that has acquired an EHR as of January 1, 2009; and
- 2013 in the case of a covered entity that acquires an EHR after January 1, 2009.

As hospitals participating in the stakeholders meeting on May 6 indicated, and many others who are likely to respond in writing to the RFI are sure to relate, no EHR system currently has the technical capability to create a patient-friendly and meaningful report of disclosures made for treatment, payment and health care operations. A hospital’s EHR system actually consists of many separate systems (e.g., radiology, lab work, 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,
and patient billing. Bringing data from all of these disparate systems together into an integrated accounting of disclosures report is a complex and time-consuming process that involves analysis of large volumes of data. At the present time, it cannot be done without human intervention.

Audit logs may capture and supply some important data that may be useful in producing an accounting of disclosures report for a specific patient. But there is significant variability in the level of detail captured in the audit trails within the various subparts of the system at the same hospital. Moreover, current systems are unable to automate the "purpose" of the disclosure, making it impossible for the system to easily distinguish between a "use" that does not need to be included in the accounting and a "disclosure" that does.

Significant changes to current systems would be required to create an effective infrastructure that is technically capable of fully capturing and storing the significant amount of data needed to produce a complete detailed accounting. The experiences of hospitals suggest that significant changes to information systems requires considerable time and effort to design, code and test and often involve months of installation and staff training in the hospital environment after the hospital gets in the vendor’s queue for the product or system upgrade.

Moreover, the electronic capture of data elements by the EHR does not equate directly to the generation of an accounting of disclosures report that can be read and understood by an individual patient. Such a report generally is created through post-event analysis of stored information retrieved from the EHR, not through real-time event processing. Stored electronic data must be “translated” for human consumption, which requires dedicated staff resources – specifically, of staff with specific knowledge and skill to decipher and process machine readable data – and considerable time to generate an individualized report that can be provided to a patient. Creation of a patient-friendly individualized accounting report is likely to remain a heavy administrative burden for all hospitals.

Even without receiving a detailed accounting of disclosures, however, patients are informed about how their information is used and disclosed by a covered entity, including disclosures for treatment, payment and health care operations, because they receive the covered entity’s Notice of Privacy Practices. That Notice, which all covered entities already are required to provide to every patient under the HIPAA privacy rule, includes not only a general description of the types of uses and disclosure for treatment, payment and health care operations but also specific examples of each.

Importantly, the Notice also contains information about how individuals can complain to the covered entity if they believe their privacy rights have been violated. The experiences of hospitals to date suggests that patients are more interested in knowing whether a specific privacy violation relating to their EHR has occurred and getting detailed information in response to a specific inquiry and investigation by the hospital’s privacy/compliance staff. Such privacy investigations are a largely manual process that involves human review of large amounts of data as well as actual discussions with personnel involved in the patient's care. They can take 20-30 hours of staff time and several weeks to complete. Patients value these investigations because
the information provided informs the patient about specific violations and what appropriate
disciplinary and other measures were taken to ensure that violations do not recur.

The current HIPAA requirements and present practices already ensure that patients are getting
the information that they feel they need and value most. As a result, the Secretary’s use of the
statutory discretion to delay the compliance date for these new accounting of disclosures
requirements seems prudent and will ensure that the technology hospitals need to comply with
these requirements is readily available at a reasonable cost. Questions about our
recommendations should be referred to Lawrence Hughes, assistant general counsel, at (202)
626-2346 or lhughes@aha.org, or to Patti Goldman, senior associate director, federal relations, at
(202) 626-2328 or pgoldman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President