CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

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

Subject: 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 California Hospital Association (CHA) and our more than 400 member hospitals and health systems, we appreciate the opportunity to comment on the HIPAA Privacy Rule Accounting of Disclosures (RIN 0991-AB62); Notice of Proposed Rulemaking, 76 *Fed. Reg*. 31426, published May 31, 2011.

Although well intended in honoring the rights of patients, CHA believes the proposed rule assumes a generalized level of technology capabilities across the spectrum of covered entities (CEs) under the Health Insurance Portability and Accountability Act (HIPAA), and ignores that current technology available for hospitals varies greatly. As proposed, for all hospitals to comply, significant costs and scarce resources would need to be diverted away from direct patient care to an administrative accounting and access requirement. CHA urges the Department of Health and Human Services' Office of Civil Rights (OCR) to withdraw its current proposal to establish an individual right to request and receive an access report and to allow for technology upgrades that will dovetail into consistent standards for meaningful use of electronic health records (EHRs). CHA believes the requirements for any new administrative reporting should be delayed until health information technology (HIT) reporting systems are standardized.

The following specific comments are provided for your review and consideration.

Right to Accounting of Disclosures

CHA applauds OCR's change in focus from the previous "exclusion" list format to the new listing of specific instances for which disclosure is required in the *Standard: Right to Accounting of Disclosure*. CHA supports the acknowledgement of circumstances of disclosure exemptions which clearly are not in the best interests of patients or society. Additionally, CHA supports the

exclusion of information used in efforts to improve patient care, as well as discussion and consideration from the Institute of Medicine and others relative to research reporting.

CHA supports the requirement that individuals provide requests in written form, and the additional allowance for refinement of requests that limits the requested information. To this end, we appreciate the provisions that specifically provide hospitals the opportunity to assist individuals in tailoring or limiting the scope of the requested information, and to charge for subsequent reports following an initial report for a specified timeframe.

With that said, CHA opposes reducing the response time for reporting from 60 days to 30 days. Although subject to narrowing the scope, and limited to a designated record set, CEs would now be directly responsible for including all disclosures by business associates that create, receive, maintain or transmit designated record set information. Under current law, CEs must ensure business associates make that information available (to provide an accounting of disclosures). The proposed rule goes a step further and would require the CE to include the disclosures of business associates in the accounting. With this level of complexity required to capture all disclosures from all business associates for the CE's accounting report, hospitals must again divert personnel resources to comply. Further, to ensure the report information is accurate, it will require validation and careful review prior to being shared with the individual.

To afford the time and resources necessary to ensure a comprehensive and accurate accounting, the current timeframe of 60 days should *not* be shortened to 30 days as stated in the proposed rule. While a single 30-day extension is allowed, we do not believe this is sufficient time for more complex CE operational models, absent significant disruptions in hospital provider workflow and patient-care responsibilities.

CHA acknowledges and appreciates OCR's proposal to reduce the current requirement of six years to three years for retention of documentation necessary to produce the accounting of disclosure report. **CHA believes the requirement for retention of the actual accounting should mirror the same timeframe. Therefore, we urge OCR to rectify this inconsistency and define retention timeframes for all related documentation as three years.** Creating differing retention requirements is unnecessarily cumbersome for CE management and provides little additional value to the individual.

CHA urges OCR to provide additional clarification of the term "designated record set" used in the definition of disclosure. The ambiguity and vague nature of the current definition leads to inconsistent interpretations and continues to result in confusion with application of the term. This is particularly apparent when protected health information (PHI) is used outside the clinical arena, such as by business associates engaged in financial, billing and insurance applications.

Finally, CHA acknowledges that the content of the accounting is narrowed to the approximate time or date range, and a minimum description of the purpose as long as it reasonably informs the individual. CHA does not, however, believe that employees who disclose PHI in patient care delivery on a daily basis should be subject to accounting by name. Hospital employers must also

protect employee confidentiality and safety. To this end, **CHA urges OCR to eliminate the requirement to identify caregivers by name if known, and allow hospitals to identify by first name or employee number.** This balances the privacy rights of employees with those of requestors.

Right to Access Report

CHA urges OCR to withdraw its current proposal to establish an individual right to request and receive an access report as currently defined in the proposed rule. The new requirement for access reporting should be redesigned consistent with broad-based technology capabilities among covered entities, and to provide patients with the desired information in a time and way that accomplishes the goals without adding significant new administrative expenses and burdens on providers' scarce financial and personnel resources.

In reviewing the ability to comply with the proposed rule, one hospital demonstrated production of one patient's access report. The report compiled access to a patient's electronic designated record set information for a 30-day hospital stay. The access report compiled information consolidated from all systems within the hospital containing PHI, and was more than 1,500 pages. In this demonstration, it is difficult to correlate the value to the patient, which is likely lost in the bulk of material provided. For this reason, CHA appreciates the proposed rule allowing the hospital to work with patients to narrow their request parameters.

OCR fails to recognize and address how the proposed rules will impact CEs as they try to implement the requirement of a single aggregated access report. The sheer volume of data in a single aggregated report, even if translated somehow into a report that is reasonably understandable by the requestor, will likely create confusion and frustration due to the myriad of access transactions in the complex care environment.

When exercising the right to access the report, requestors should be required to describe the exact nature of the interest or concern for which the report is requested. Recently, a hospital reported to CHA that after an extensive investigation was conducted at the request of a patient who claimed unauthorized access of his information, at the time the findings were presented the patient stated that what he *really* wanted to know was whether a particular family member employed by the facility had viewed his record. Requiring (rather than requesting) the specific nature of the intent at the onset of the access investigation would narrow and focus the review, and save innumerable hours of staff time in conducting the requested access investigation. With that said, most systems currently in use do not facilitate audit review at the level of individual access; thus, intense manual intervention is required and will divert resources from patient care.

The complexity and disparity between differing systems' audit logs further increase the burden of the proposed report compilation. One academic hospital in California has more than 200 systems with PHI within its facility, each with differing formats for report tracking access. This is not uncommon. To prepare an access report that can be easily understood by patients, the hospital would be required to do a manual review and reconciliation of each system's data, consuming

untold hours of staff time. Not only is this labor intensive, but it is time intensive. Thus, the proposed 30 days to respond would not be sufficient for compiling such a report.
Hospitals are focused on implementing certified EHR systems to manage clinical data in meaningful ways. CHA strongly urges OCR to limit any reporting requirements to those currently required of certified EHR products only. To require any additional information technology requirements for reporting or data production in the current intense HIT environment is to risk undermining national efforts for standardized quality reporting and meaningful use outcomes.

As noted in the proposed rule, standardized access tracking auditing functions are not currently required as a component of certified EHR systems. Without specific and mandated standards to drive the development of auditing tools within systems, hospitals simply cannot provide easily understandable reporting from disparate systems as proposed. While the goal of reporting to the patient is laudable, the administrative costs to providers will far exceed any value to the patient at the present time.

Finally, and as briefly mentioned above for the accounting requirement, CHA is very concerned about the unintended consequence of identifying hospital staff by "name of natural person" in the proposed access report. Many hospitals have implemented policies that identify staff by their first name on identification badges due to threats and harassment outside the workplace by patients and patient family members. Providing the first and last name on these reports will put staff unnecessarily at risk. This is of particular concern for those working in care settings where patients have diagnoses that might place staff at high risk, such as emergency rooms, and those treating behavioral health and child/adult abuse or other law enforcement-related injuries/interventions. In many cases patients do not understand the need for staff who are not involved in direct patient care to access clinical information. While we are pleased that personal roles and job titles/descriptions are excluded in the report requirement, we do not believe it is appropriate to list hospital staff by name and we urge you to reconsider.

In summary, CHA believes OCR's efforts to support individual rights relative to disclosure of and access to PHI are well intended; however, confusion specific to definitions in the 2002 HIPAA privacy rule remain. Reporting on poorly understood terms, such as "designated record set," in a newly evolving technology arena, such as HIT, is premature and a recipe for disaster. The right of access reporting needs to be thoroughly developed with input from operational experts in HIT and in concert with patient advocates to create information that is of value to patients without increasing costs to the health care system. We look forward to working with OCR to ensure this occurs.

We appreciate the opportunity to provide our comments. If you have any questions, please do not hesitate to contact me at plane@calhospital.org or (916) 552-7578, or my colleague Alyssa Keefe, vice president, federal regulatory affairs, at akeefe@calhospital.org or (202) 488-4688.

Respectfully submitted,

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