

August 1, 2011

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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

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Deputy Director for Health Information Privacy  
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

Re: HIPAA Privacy Rule Accounting of Disclosures under the Health Information  
Technology for Economic and Clinical Health Act

Dear Ms. Verdugo and Ms. McAndrew:

On behalf of the undersigned organizations, we appreciate the opportunity to submit comments on the proposed rule (Proposed Rule) relating to accounting for disclosures of protected health information (PHI) and a new right to receive access reports, which was published in the May 31, 2011, issue of the *Federal Register*.

First, we applaud the Office for Civil Rights (OCR) for proposing new changes to the accounting for disclosures requirement. With a few exceptions, we believe that the proposed changes will reduce administrative burdens on covered entities, including physician practices, and provide increased clarity while still providing consumers with valuable information about specific instances in which their PHI has been released outside of a covered entity. We specify below a few areas where we disagree with the Proposed Rule and seek important clarifications or further guidance.

In contrast to our overall reaction to the accounting for disclosures proposals, we are extremely concerned about the Proposed Rule's new right to an access report. While we agree that patients should be able to obtain information about their PHI, we believe the right to an access report will impose significant administrative costs and burdens on the average physician practice and the production of such reports may not even be feasible in the near term for many practices. For reasons discussed in more detail below, we urge OCR not to finalize access report-related requirements in the final rule. Rather, we urge OCR to either withdraw the access report provision of this proposed rule or promulgate

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an interim final rule instead of releasing a final rule so as to afford stakeholders the opportunity to provide OCR with more information on the implications of these policies.

If OCR wishes to pursue this matter, we urge that it find ways to consult with stakeholders outside of the formal rulemaking process about access report-related issues (for example, technological capabilities, the time and effort that would be required to process a single request for an access report, the reaction of an average consumer to various types of access reports, etc.). We believe it would also be helpful for OCR to conduct in-depth, on-the-ground investigations of the current range of covered entities' capabilities with respect to access reports, and also to consult with vendors of health information technology (HIT), whose products would be required to capture data elements that must be included in any future access reports. Additional comments regarding the proposed access report requirements are provided below.

### **Accounting for Disclosures**

OCR proposes to change the current accounting period from six years to three years, and we support this change. This revision would substantially reduce the administrative burden on covered entities.

OCR also proposes to adopt a specific list of disclosures that must be addressed in accounting of disclosures. We also consider this to be a positive change as long as the list of disclosures is not unreasonably long or too complicated to understand. Therefore, we urge OCR to keep the list of disclosures that must be included in an accounting as short as possible and to ensure that the categories included on the list are clear and easy to comprehend. For example, the Proposed Rule includes on the list of required disclosures for an accounting those for judicial and administrative proceedings as provided in § 164.512(e) of the Privacy Rule. Section 164.512(e) refers to disclosures pursuant to orders or other types of requests from both courts and administrative tribunals. It is possible that staff in the average physician's office may not know what is meant by an administrative tribunal. This is an example of where certain covered entities could be unsure about what disclosures need to be included in an accounting. As a result, we request that OCR develop subregulatory guidance for covered entities that would describe, in clear and concise language, those disclosures that would need to be included in an accounting. We believe that this type of information would be extremely helpful. In making this request, we acknowledge that OCR has provided a wealth of useful guidance about both the Privacy and Security Rules on its Web site. We believe that guidance explicitly focusing on accountings of disclosures would be similarly of great value to all stakeholders.

We also note that OCR has concluded that accounting for disclosures that are made through an electronic health information exchange (for example, when a covered entity or business associate transmits some or all of an electronic health record (EHR) to another electronic system, such as another covered entity's EHR, a pharmacy, laboratory, or health plan) would be overly burdensome "at this time" when compared to the potential benefit to individuals. We support OCR's decision not to require an accounting for electronic health information exchange disclosures. Such a requirement would run counter to governmental efforts to encourage HIT adoption among health professionals because it would further increase the already heavy regulatory burdens for compliance, and, as a result, could undermine national efforts to better coordinate our fragmented health care system.

With respect to the content of an accounting of disclosures, OCR specifies up to five data elements, including "type" of PHI disclosed. The Proposed Rule does not explain what OCR means by the term "type" or whether this new terminology differs in meaning from the existing requirement to include "a brief description of the PHI disclosed." We request that an interim final rule or revised proposed rule clarify this data element, although we caution against an overly prescriptive definition that could complicate compliance.

With respect to providing a requested accounting of disclosures, OCR proposes to decrease the permissible response time from 60 days to 30 days (while retaining the availability of a 30-day extension). We strongly object to this change. Rather, we urge that the current 60-day timeframe be retained as well as the current option of a further 30-day extension. We recognize that OCR may be responding to pressures to require more rapid production of accountings of disclosures. However, our members are already facing enormous challenges in meeting the needs of their patients and in complying with a wide range of regulatory requirements. Providers will need sufficient time to respond to what will likely be very infrequent requests for an accounting of disclosures. Generating an accounting of disclosures is largely a manual process for most covered entities at this time, and we believe it will remain so for some time to come. In addition, the requirement that an accounting of disclosures prepared by a covered entity is also expected to include information from its business associates is another reason for allowing covered entities as much time as possible to obtain the necessary information required to respond to a request for an accounting of disclosures.

Finally, OCR proposes to require that covered entities and their business associates comply with the modifications to the accounting of disclosures requirement beginning 180 days after the effective date of the final regulation (240 days after publication), which OCR expects to publish in late 2011. We are concerned that the proposed compliance deadline might not be feasible, especially if the final rule significantly

departs from the accounting for disclosure requirements currently in place. In addition, we note that the Proposed Rule acknowledges that even in the case of certified EHRs, the EHR certification criterion relating to accounting for disclosures is currently optional. Thus, it is conceivable that even practices employing certified EHRs would not be able to rely upon such products to facilitate their preparation of an accounting of disclosures. In addition, a more generous compliance deadline would give OCR more time to prepare the related subregulatory guidance we recommend above.

In summary, we ask that the final rule provide covered entities, especially smaller physician practices, as much time as possible to understand and prepare to comply with new accounting for disclosure requirements.

### **Right to an Access Report**

As noted earlier, although we believe patients should have access to information about their PHI, the undersigned organizations are deeply concerned about the proposed right to an access report. We believe that the Proposed Rule overestimates the technical capabilities currently available for producing these access reports. Based on the information we have at hand, we doubt that producing such reports would be feasible for the average physician office, and we worry that physician offices would have to spend a great deal of time and effort to prepare to respond to a request for an access report, which OCR itself concedes might rarely occur. To aggregate information for an access report, covered entities and business associates will likely have to purchase expensive new software and/or hardware, and the administrative burdens and related costs needed to compile the access reports will divert limited resources needed to accomplish other important initiatives.

Moreover, we consider the proposed 30-day timeframe for responding to access report requests to be inadequate, notwithstanding the option of a further 30-day extension provided that certain requirements are met. This timeframe is especially short given that, once again, a covered entity would be expected to assemble relevant data from all of its business associates.

Finally, we are not confident that the proposed compliance deadlines (January 1, 2013, in the case of electronic designated record sets acquired after January 1, 2009, and January 1, 2014, for all other electronic designated record sets) would be feasible. We note that these compliance deadlines apparently related to a statutory provision regarding accounting for disclosures through EHRs for certain purposes, not to access reports relating to all access events across the full range of electronic designated record sets.

In summary, we urge OCR not to finalize the proposed access report requirements. As stated above, we recommend that OCR should either withdraw the access report provision of this proposed rule or publish an interim final rule with an opportunity for further public comment. The matters addressed in the Proposed Rule involve complex technical, administrative, and policy questions and the implications of a regulatory decision might not become apparent until all stakeholders are able to review and discuss such a decision. For example, a physician practice might need to obtain input from one or more vendors in order to determine the implications of these policies for that particular practice. In addition, the fact that covered entities are now required to produce both accountings for disclosures and access reports, each with differing requirements can be inherently confusing. Accordingly, we believe that either withdrawal of the access report provision of this proposed rule or publishing an interim final rule, rather than a final rule, would be critical in this instance.

#### **Designated Record Sets Clarification**

Finally, we request that the OCR clarify that both the proposed accounting for disclosures and access report requirements are contingent upon a covered entity or business associate maintaining PHI in a designated record set, which is a medical or billing record used to make decisions about a patient. With respect to access reports, the proposed rule is clear that the covered entity or business associate must maintain PHI in a designated record set in order for the access report requirement to apply. Specifically, “[t]he right to an access report would only apply to protected health information about an individual that is maintained in an electronic designated record set.”<sup>1</sup> The proposed language does not specifically use the word “maintain” with respect to designated record sets and the application of the accounting for disclosures requirement, but the preamble to the proposed rule states that “[t]he right to an accounting of disclosures would encompass disclosures of both hard copy and electronic protected health information that is maintained in a designated record set.”<sup>2</sup>

Several of the undersigned organizations operate clinical data registries that receive PHI from hospitals, physicians, and other providers. In doing so, these registries act as business associates of the covered entities that submit data to the clinical registries. These business associate registries do not maintain designated record sets from the participating sites, but some of the information submitted to the registries may be pulled from medical or billing records. We urge OCR to confirm that business associates that receive PHI that comes from designated record sets maintained by covered entities, but that do not actually maintain designated record sets themselves, are not subject to the

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<sup>1</sup> HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act, 76 Fed. Reg. 31,426, 31,448 (May 31, 2011).

<sup>2</sup> *Id.* at 31,429.

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proposed accounting for disclosures or access report requirements. All otherwise applicable provisions of HIPAA would continue to apply to this information.

We appreciate the opportunity to offer these comments regarding accounting for disclosures and the proposed new right to an access report. If you have any questions about our comments, please contact Bob Jasak at [bjasak@facs.org](mailto:bjasak@facs.org) or at (202) 672-1508.

Sincerely,

American Association of Neurological Surgeons  
American College of Osteopathic Surgeons  
American College of Surgeons  
American Congress of Obstetricians and Gynecologists  
American Osteopathic Academy of Orthopedics  
American Society for Surgery of the Hand  
American Society of Anesthesiologists  
American Society of Breast Surgeons  
American Society of Cataract and Refractive Surgery  
American Society of Colon and Rectal Surgeons  
American Society of Plastic Surgeons  
American Urological Association  
Congress of Neurological Surgeons  
Society for Vascular Surgery  
The Society of Thoracic Surgeons