



July 21, 2011

Georgina Verdugo, JD  
Office for Civil Rights  
U.S. Department of Health and Human Services  
Attention: HIPAA Privacy Rule Accounting for Disclosures

Submitted electronically at: <http://www.regulations.gov>

Dear Ms. Verdugo:

The College of Healthcare Information Management Executives (CHIME) appreciates the opportunity to respond to the notice of proposed rulemaking (NPRM) relating to HIPAA Privacy Rule Accounting for Disclosures and the proposed new right to receive Access Reports.

CHIME's 1,400 members represent chief information officers (CIOs) and other top information technology executives at many of the nation's largest hospitals. CHIME members have frontline experience in implementing clinical systems, and have learned by trial and error what works and what doesn't in implementing such electronic systems and optimizing the value derived from them. Healthcare CIOs share the vision of an e-enabled healthcare system as described by the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator (ONC) for Health Information Technology.

Before providing specific comments regarding the proposed changes to Accounting of Disclosures and the new Access Report, CHIME would like to make a few important observations.

One of the goals behind Meaningful Use is to eliminate inconsistency and variability long-since built into healthcare information technology systems. Through the Electronic Health Record (EHR) Incentive Payments Program, CMS and ONC have begun to mitigate this fractured and incompatible state for EHRs. But many technologies beyond the scope of EHR Incentive Payments remain splintered and variable – the same as before Meaningful Use.

The 2002 HIPAA Privacy Rule broadly defined a designated record set (DRS) as the medical record and billing record about individuals maintained by or for the provider, as well as any

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other group of records that are used, in whole or in part, by or for a covered entity to make decisions about individuals. Nearly a decade later, a wide variance among providers exists as to what data sets should be contained within their DRS. Because of this ambiguity, OCR and consumer expectations may be at odds with an individual provider's interpretation and understanding of what their DRSs should be.

CHIME applauds OCR's efforts to clarify and simplify Accounting of Disclosures in this proposed rule. OCR appears to acknowledge the tremendous amount of time and resources needed to produce an Accounting of Disclosures and we appreciate any attempt to both diminish Accounting of Disclosure administrative burdens and increase the value to patients of such accountings. Unfortunately, we cannot echo these sentiments for the proposed Access Reports.

DRSs remain too broadly defined and too variable in today's health IT environment. Moreover, the ability to aggregate hundreds or even thousands of access events in any automated fashion is not realistic for most covered entities – never mind across covered entities and their numerous business associates. **For these and other reasons discussed in more detail below, CHIME urges OCR not to include Access Report requirements in the final rule.** If OCR wishes to pursue the concept of access reports further, we would instead recommend that stakeholders be convened to better assess what is technically feasible in the short-term, long-term, and during the transition across the full range of covered entities. On the other hand, if OCR elects to retain requirements for Access Reports, **CHIME firmly believes that only data gathered through certified EHRs, not the full array of designated record sets, should be expected to populate such Access Reports.** We believe the access logs, report filters, and other technical specifications needed to generate an Access Report would be inconsistent or nonexistent across many clinical data sources that might be considered part of a DRS.

### Accounting of Disclosures

CHIME supports a number of the proposed changes to Accounting of Disclosures, particularly in those areas where clarity and reduced burdens appear to be the aim. For example, by listing the types of disclosures subject to the accounting requirement, rather than listing exemptions, CHIME believes that providers will be better able to comply. We compliment OCR for this approach and urge that the list not grow beyond what is proposed. Likewise, by concluding that disclosures made through electronic health information exchange would be “overly burdensome compared to the potential benefits to individuals,” OCR has made the correct calculation.

However, other proposals regarding implementation and production timelines are in need of revision. Generating an Accounting of Disclosures is today largely a manual process for most covered entities and we believe it will remain so for some time to come. Producing limited or customized reports of the kind described in this NPRM could be difficult and time-consuming, at least for some covered entities. While such customization will likely be feasible over the longer term, we believe that OCR should encourage, but not require, all

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covered entities to have the capability to comply with requests for customized accountings at this time.

CHIME would like to offer a number of ways to make the Accountings of Disclosure less burdensome, while maintaining their value.

#### Data Elements

In terms of Accountings of Disclosures, the proposed rule calls for up to five data elements: Date, Name, Address (if known), Type and Purpose of disclosure. With the exception of “Type” of protected health information disclosed, CHIME believes the data elements are appropriate. We also are in favor of the exceptions outlined in the NPRM for the Name and Purpose elements. However, CHIME foresees problems specifically with the *Type* data element. The proposed rule includes no explanation for what is meant by this data element and we believe the final rule should address this matter. While we believe that more specificity about this data element would be helpful (for example, it would provide important guidance to health information technology vendors, covered entities and other stakeholders), we believe that any categorization of “type” should be simple and straightforward and not unduly difficult to understand or report. In addition, covered entities should be accorded as much flexibility as possible in reporting “type” information.

**RECOMMENDATION:** CHIME recommends that OCR provide more discussion around the “*type of protected health information disclosed*” data element in the final rule.

#### Timelines

CHIME supports OCR’s proposed approach to accounting periods. By changing the requirement from six to three years, OCR acknowledges how much data could be generated by patient interactions over a six-year period and has clearly weighed that burden against potential value to the patients.

But with both the production and implementation timelines, OCR has underestimated the resources needed to gather the proposed Accounting of Disclosures information. This is evidenced by OCR proposing to cut short the response time by 30 days, while also requiring covered entities to provide the Accounting of Disclosures in customized views and formats.

**RECOMMENDATION:** CHIME believes that the current 60-day timeline for responding to Accounting of Disclosures requests should be retained. The proposed 30-day time frame is simply too short, especially since information would need to be gathered from a variety of sources, including business associates (whose agreements will need to be revised), and may require legacy system access for organizations that are transitioning to EHR systems or a niche vendor handling the disclosure system tracking.

While we are supportive of the accounting period change from six to three years, CHIME urges OCR to give covered entities as much time as possible to comply with the final rule following publication.

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## **Right to an Access Report**

As noted above, CHIME is extremely concerned about the entire concept of Access Reports. CHIME believes the administrative burdens and related costs needed to compile, transmit and then explain the proposed DRS-populated access reports would divert the same resources needed to accomplish other important initiatives, including EHR Meaningful Use, and ICD-10 and HIPAA 5010 implementation, while providing very little value to patients. This NPRM assumes current market solutions and strategies are able to perform such a consolidation of information, which is counter to CHIME member experience.

To aggregate information for an Access Report, both across the covered entity and incorporating information from business associates, would require the purchase of new and expensive software tools, additional data storage and multiple FTEs dedicated to pulling and consolidating logs from disparate systems. The proposed rule seems to overestimate the technical capabilities currently available for producing a consolidated Access Report. To align audit logs, an ANSI standard including data fields and standard values would need to be developed and the various systems inside a DRS would have to have consistent and unified purge rules. Failing these basic functions, data aggregation would require intensive manual intervention and manipulation. CHIME considers this a whole new class of software, which is at best under-developed in today's market.

The problems with the Access Report concept could be ameliorated, at least to some extent, by limiting these reports to the output of access logs for certified EHRs, rather than enterprise-wide DRSs. So we reiterate our earlier recommendation that this option be given serious consideration if OCR decides to retain any access report requirements in the final rule. This view notwithstanding, the remaining comments assume that DRSs – as currently defined – could remain the basis for Access Reports.

### **Data Elements**

Reflecting our general concerns about Access Reports, CHIME believes that many of the systems contained in a DRS may be incapable of pulling the proposed data elements. Beyond the technical aspects of the five proposed data elements, CHIME has significant concern regarding the disclosure of the names of a covered entity's staff members who have accessed a given patient's information. This differs from the Accounting of Disclosures name data element because those accountings would only be generated for a set list of purposes and only for the release of protected health information outside of the covered entity. With Access Reports, disclosing every name has the potential to expose employees to unnecessary scrutiny or other negative consequences. This could also be viewed as a violation of employee rights.

**RECOMMENDATION:** Instead of requiring access reports that include names, CHIME believes that a safer alternative would be to require patients to provide a covered entity with specific names for the covered entity to determine whether those individuals have or have not accessed the patient's information. The covered entity would then report back to the patient and also be in a position to take disciplinary action, if warranted. While not immune

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from problems, this approach would be a significant improvement over the proposed rule. In addition, we believe that a number of covered entities now follow such a process.

#### Consolidation of DRS systems

As noted earlier, we believe that the proposed aggregation of access log information would be problematic, especially if it involved business associate data.

**RECOMMENDATION:** CHIME believes this well-intentioned requirement to generate one Access Report will not be feasible for most covered entities, particularly if record sets maintained by business associates are required for inclusion. Should this requirement remain, OCR should limit it to data from access logs from certified EHRs, which have a level of standardization that many ancillary and downstream systems do not.

#### Limiting Accountings by Data Element

While CHIME acknowledges the purpose of allowing patients to segment their Access Reports by data element, we believe this task would be extremely difficult given the specified access period requirements. Even by setting the access period to three years, a provider is likely to have problems capturing information in a way that would allow it to generate a limited report.

**RECOMMENDATION:** CHIME suggests that covered entities be allowed to provide these proposed limited Access Reports on a prospective basis following the publication of a final rule. We do not believe many providers will be able to comply with requirements for a customizable Access Report based on data collected prior to a final rulemaking with standards. CHIME also wants to emphasize the importance of giving covered entities as much flexibility as possible with respect to what forms and formats are “readily producible.”

#### Timelines & Compliance Deadlines

If Access Report requirements are retained, CHIME agrees that limiting them to a 3-year period would be better than some longer period. However, even by limiting the Access Report to three years, a single patient could have thousands of access events requiring dedicated FTEs to compile and numerous resources to explain the Reports to patients. Additionally, the amount of disk space and disk pathways needed to house three years of access data would be costly for a single covered entity, such as a hospital or hospital system. Even under optimal circumstances, where providers can use certified EHR systems to perform name-specific and period-limited queries, access reports can take 12 hours or more to generate even when only 90 days of data are being examined. The time and resources required to generate a more complicated report for a three year period across a full array of DRSs would obviously be much greater.

Under the proposed rule, Access Reports could include information that prompts requests for covered entities to further explain the reports, necessitating further resources and creating more burdens for providers. While the proposed rule does not require covered entities to explain access reports, CHIME believes that those requesting such reports will expect covered entities to do so.

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CHIME also believes that the proposed 30-day time frame for producing the proposed access reports would be totally insufficient.

We are equally concerned about OCR's proposal to make Access Reports available upon request beginning January 1, 2013 for any DRS acquired after January 1, 2009 and beginning January 1, 2014 for any DRS acquired before January 1, 2009. We note, too, that the timelines, including the use of 2009 as a demarcation point, are based on a statutory provision relating to accountings of disclosures involving EHRs, not access reports relating to all DRSs. We seriously doubt that the proposed compliance deadlines would be feasible. Even in the case of EHRs, a 2009 demarcation point is problematic because most EHRs were not certified before final standards were set in 2010. And for other electronic DRSs, no date justifies the staggered compliance deadlines because standards for ancillary and departmental systems do not exist as they do for EHRs.

**RECOMMENDATION:** CHIME believes 30 days simply is not enough time to prepare Access Reports as currently proposed. Additionally, we have concerns regarding the proposed compliance date. If any requirement is retained in the final rule for such reports, providers need as much time as possible to comply. OCR also needs to recognize that many covered entities may find it difficult to produce certain information about past access events, as opposed to those access events that occur after publication of a final rule.

In sum, given the many challenges identified with Access Reports, CHIME believes OCR should withdraw the proposed requirement and undertake further consultation with stakeholders.

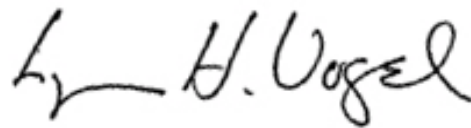
We believe OCR is attempting to make several needed changes to Accounting of Disclosures, but the proposed Access Reports would be unduly burdensome given the state of healthcare access logs and standards; limited expected demand; and a high probability of unintended consequences.

We hope these comments are helpful. If you have any questions about our comments or need more information, please contact Sharon Canner at [scanner@cio-chime.org](mailto:scanner@cio-chime.org).

Sincerely,



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