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July 29, 2011

Georgina Verdugo, JD, LLM, MPA Director
HHS Office for Civil Rights
Attention: HIPAA Privacy Rule Accounting of Disclosures

Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, Southwest
Washington, District of Columbia 20201

RE: HIPAA Privacy Rule Accounting of Disclosures – 45CFR164; RIN0991-AB62

Dear Madam Director:

On behalf of the more than 61,000 members of the American Health Information Management Association (AHIMA) I am submitting our comments on the Notice of Proposed Rulemaking (NPRM) regarding the HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology Economic and Clinical Health Act (HITECH) as published in the May 31, 2011 *Federal Register*, beginning on page 76FR31426.

AHIMA is a non-profit professional association made up of health information management (HIM) professionals. HIM professionals take seriously their stewardship associated with health information including our commitment to the patient or individual, as well as the confidentiality and security of the individual's health information. HIM professionals are educated and certified in many areas of HIM, of which all emphasize patient and protection commitments. In addition, AHIMA offers a specific certification and credential in Healthcare Privacy and Security (CHPS).

Whether serving as privacy or security officers, HIM department directors, or release of information specialists, HIM professionals have been committed to the appropriate use and disclosure of health information for many decades. This work has brought our professionals in contact not only with the patients and clinicians who are the subject and creator of an individual's health information, but also with public and private persons and organizations who seek information regarding an individual as well. It is with this education, certification, and experience that we address the concerns and questions that arise from your office's May 31, 2011 proposal. We appreciate the opportunity to make comments to the proposal, and have divided our comments into general comments and specific responses to areas of inquiry.

General Comments

Essentially OCR has offered two proposals with this NPRM: an expansion of the requirement to account for certain disclosures, of protected health information ("PHI") that amends the current HIPAA regulations as required under the HITECH legislation of 2009; and new rules that address accounting for access. Below we will include our specific comments and recommendations related to the Accounting of Disclosures. Overall, we believe that OCR has done an excellent job of updating this rule and we applaud your efforts.

With regard to the Accounting for Access rules, we find ourselves in a quandary. Although we strongly support the right of individuals to ask questions regarding access to their PHI, we are troubled because such rules go outside of the current scope of HIPAA, even with the HITECH amendments. Additionally, the transition to electronic health record (EHR) systems did not contemplate the necessity of tracking this level of access (beyond the existing privacy and security rule compliance obligations of covered entities) or take into consideration the potential administrative costs, and thus, will cause significant burden for covered entities and their EHR vendors.

Access-related requests are not uncommon to covered entities. In most cases, HIM professionals have indicated that they have been able to fulfill such requests to the customer's satisfaction and without disclosing the identity of the workforce (unless it was appropriate to do so and take action). Our members have also noted that the number of requests has been significantly low. Generally, requests for an access or disclosure report, has been limited to a particular party(s) and have been not a request for all who may have accessed the health record. For example, a patient may want to know whether a former spouse has been looking at his or her record for some inappropriate purpose.

For this reason, we believe it is appropriate to require covered entities and business associates to respond to concerns; however, we believe this requirement could be minimized in a fashion to respect the individual's rights and limit the organizational expense the OCR NPRM would suggest.

IV. Section-by-Section Description of Proposed Rule

IV.A.1 Standard: Right to Accounting of Disclosures (76FR31429)

The number of requests for accountings of disclosures received over the past eight years has been minimal, so AHIMA appreciates the limitations added to the accounting of disclosures in recognition that the burden for such an accounting outweighs the number of requests actually processed. The cost associated with the administration of this regulation is excessive as compared to the number of requests received. HIM professionals are committed to responding to individual inquiries regarding disclosures whether or not consent is necessary. Our experience attests that individuals (except in rare cases) are not concerned with disclosures.

AHIMA agrees with OCR's recommendation to reduce the length of time disclosure information must be maintained from six years to three years. AHIMA's inquiry of HIM professionals indicate there would be no problem with this reduction and we concur with OCR's assumption that maintaining information on six years of disclosures is a significant burden on covered entities and business associates.

OCR inquired if there is a burden for the covered entity to include breaches on the accounting of disclosures and, if so, how that burden compares to the benefit for the individual associated with breaches AHIMA sees no disadvantage to reporting breach incidents as part of the accounting of disclosures, and could conceive of no drawbacks if the individual receives the breach information twice.

AHIMA is concerned that instituting a system to separate out breach incidents makes the accounting for disclosures more burdensome.

AHIMA also agrees that carving out additional public health disclosures would add complexity to the reporting organization and the individual. Such disclosures may adversely affect certain population-based

public health activities, such as active surveillance programs. AHIMA supports the recommendation not to carve out such public health disclosures.

AHIMA supports excluding disclosures about child and adult victims of abuse and neglect or domestic violence. AHIMA also supports excluding disclosures about decedents to coroners and medical examiners, funeral directors, and for cadaveric organ, eye or tissue donation. Additionally, AHIMA supports excluding disclosures for the purpose of protecting the President and others as outlined in §164.512(d)(3).

AHIMA agrees that covered entities should not report oversight for multiple individuals for health oversight activities under §164.512(d). We agree if an investigation is focused on an individual rather than the covered entity, this information would be recorded on an accounting of disclosure report.

AHIMA agrees with the proposal not to include nondiscretionary disclosures. We agree a statement regarding disclosures as outlined in state and federal law should be included in the notice of privacy practices; however, we recommend that covered entities be allowed to keep a separate listing of such items required by law. This would allow the covered entity to provide the information when requested, and not have to change the notice of privacy practices each time a federal or state requirement is implemented.

The requirements currently associated with research are a significant burden. This burden could negatively impact the operation and management of effectively conducting research. AHIMA agrees with the Institute of Medicine's (IOM) report, which states the current accounting provision for research disclosures places a heavy administrative burden on health systems and health services research, but achieves little in terms of protecting privacy. AHIMA's HIM professionals also indicate that accounting for disclosures involving fewer than 50 individuals would also be burdensome as many facilities run multiple research projects at a time.

Furthermore, AHIMA believes that maintaining a protocol listing of studies involving the disclosures of 50 or more individuals will also be burdensome because the Institution Review Board (IRB) maintains this same type of information on all research studies at the facility. If the obligations currently contained in the HIPAA Privacy Rule are continued, covered entities will be required to update its protocol listing of studies every time a new research study is added. AHIMA understands the importance of individual privacy and the right to know if the individual's healthcare record was considered or included in research. We therefore propose consent be included to allow for the individual's healthcare record to be reviewed for potential research. Individuals will then need to consent if they or their healthcare record is to be used in the research. Finally, recording the information that the individual is part of a research study in the healthcare record will allow for any clinical needs to be met, thereby ensuring overall patient safety.

IV.A.3. Implementation Specification: Provision of Accounting (76FR31435)

AHIMA believes OCR's recommendation to reduce the time in providing an accounting for disclosures from 60 days to 30 days (with a one 30-day extension) will greatly support the consumer and thus we support the recommendation. Our HIM professionals believe a 30-day time frame with one 30-day extension is appropriate for covered entities and business associates alike.

Under current circumstances, most disclosure reports are created using proprietary vendor software applications that may or may not be machine-readable as defined. Requiring a machine-readable format could be extremely expensive (e.g. purchasing equipment and ensuring readability) given the limited requests for reports. There is no common format or standard that we are aware of to permit a universal machine-readable report. AHIMA does not support this recommendation.

IV.B. Right to an Access Report—Section 164.528(b) (76FR31436)

As noted above, AHIMA does not believe there has been enough time for the healthcare industry to work with OCR to either develop a set of requirements that satisfy the needs of the individual or acquire the resources needed to collect and create the reports. We have received comments from our members that access reports are voluminous and contain hundreds of pages.

Our HIM professionals believe that individuals will not understand how long these reports can be, and we are concerned about the impact this volume will have both on the individual and the covered entity. Education to individuals is necessary prior to implementation of the rule to ensure that individuals fully understand the various types of accesses that can be listed in an access report. AHIMA fully supports the individual's right to understand what to expect when he or she receives an access report.

IV.B.2. Implementation Specification: Content of the Access Report (76FR31437)

AHIMA queried our HIM professionals on how they currently handle individuals' concerns about who has accessed their electronic health records. The HIM professionals indicated that they have been able to respond to the queries and satisfy the individuals without providing the details proposed in the access report.

Accordingly, AHIMA suggests it would make more sense to require covered entities and business associates to respond to these requests on an ad hoc basis rather than require significant systems and process changes that will raise the cost of healthcare for what appears to be a very limited number of requests.

However, if OCR does mandate the more expensive approach, AHIMA concurs that systems do not have to be rebuilt to include the name of the persons who access a record. AHIMA believes that access reports should carry only identifiers for the workforce members who appear on the report, not the names. Our experience demonstrates that individuals seeking access information often have specific individuals in mind when making such requests. We believe it would be appropriate, in those cases, to identify the individuals who have accessed the information per the requests and include the user identification of other workforce members.

While we fully support the requirement allowing an individual to have knowledge of access, we also want to protect the workplace staff of the covered entity. AHIMA supports narrowing the requests to specific individuals when possible. In some treatment environments (e.g. emergency departments and psychiatric facilities), providers are permitted to use pseudonyms to avoid patients stalking or contacting them outside the workplace. Access accounting would require facilities to share the legal names of their providers which defeat the protections that have been in place for long periods of time.

Our HIM professionals report several situations where employees have been stalked when full identification has been given. We have encouraged these individuals to give specific examples in their responses to OCR.

We believe that capturing detailed information on each internal exchange of systems data would be difficult to achieve, and would not benefit the individual. It would also add unnecessary pages to the access report. AHIMA agrees that the burden of providing identifying information about internal systems is substantial and the interest of individuals in learning of such internal exchanges is minimal, if it exists at all.

AHIMA believes there would be a significant administrative burden in requiring access reports to include a description of what information was accessed. Our HIM professionals report that most existing systems do not currently capture what information was accessed. Accordingly, it would require significant system changes in all designated record sets to identify information, which would also be inconsistent between systems unless a standard is developed. For example, if the cost for the upgrade is \$150,000 and only three requests were received, the average cost of a request would be \$50,000 per request.

AHIMA agrees that the requirement to include the address information indicating where the access occurred is difficult and serves no purpose. We are concerned about how the address information would be captured. In addition, many staff have remote access (e.g. coding, transcription, management, clinicians) and we are not sure what address would be captured. AHIMA does not believe the home address of the staff should be captured. Furthermore, many providers and staff use mobile devices. These mobile devices do not have a specific address tied to them at the time the information is accessed. AHIMA recognizes that the software still captures the access, but the location at which the access occurred does not add value.

Although we understand that including the descriptions of the purpose of the access may be of interest to the consumer, we are concerned that the workflow and time required by providers to capture the reason for accessing the healthcare record may hinder the care a patient receives. Even if the description uses a standardized nomenclature, the additional time this would take would frustrate users. HIM professionals reported that when reasons were requested in a single workflow, most users chose the first options because it was quick. We would question the accuracy of the information collected as well as the value of the treatment provided to the individual if the provider has to record the reason for access. We are also concerned this would hinder the rest of the covered entity's daily operational success if staff has to take time to identify the reason for every access into the healthcare record. AHIMA supports the proposal that covered entities and business associates do not include the purpose of the access.

We agree that systems currently do not capture the purpose of the access and the ultimate recipient of the information within audit logs. We believe the second point (excluding information that does not need to be on an access report) is moot since systems currently do not capture the information in the first place. Any information regarding disclosures will be captured through the accounting of disclosures report.

We agree that very few individuals request reports. We also agree that creating the reports into one master report for the individual is a manual process when pulling data from multiple systems. However, HIM professionals are concerned about the ability of third parties, through the individual, requesting blanket reports to be used for data mining. This activity by third parties could quickly become very time consuming and burdensome.

We have concerns with the term "machine-readable" as used in the NPRM. In taking the definition of machine readable in the NPRM under access, we agree covered entities may provide access reports in the formats specified.

V. Effective and Compliance Dates (76FR31441)

HIM professionals do not believe that covered entities and business associates current systems are set up to keep the data that may be required in this NPRM back for three years. Since the rule is not an interim rule or a final rule, policies and procedures addressing these specifications may not be in place to meet the proposed three year retention requirement. Based on the fact that requirements are not known, AHIMA recommends OCR meet with the healthcare industry including vendors to determine how to standardize

systems to report required access reports. Logging processes in each system are different, and collecting the required information is not standardized. In addition, it has been pointed out to us in a set of letters written and concluded by the OIG, that a good number of facilities do not have ability to meet current technical requirements therefore; to move ahead with current compliance dates will not be of value.

AHIMA understands the legal reasons for looking into small health plans and the possible delay that may be applied as written in HIPAA, but we anticipate that small providers will have the same difficulties as small health plans with this NPRM and recommend consideration for extension in complying with the Accounting of Disclosures Rule.

VI. Regulatory Analyses

VI.B.3. What would be the impact of changes to accounting of disclosures requirements? (76FR31444)

As discussed above, AHIMA believes OCR's recommendation to reduce the time frame to account for disclosures from 60 days to 30 days (with a one 30 day extension) will greatly benefit the consumer. We support the recommendation.

VI.B.4. What would be the impact of adding the right to an access report? (76FR31444)

Our HIM professionals report that on an annual basis, few requests are received and processed, so we have no way to judge the number of requests that could be submitted. If this access right was extensively advertised (e.g. prominent television show or broadcast), this could cause considerable delays and frustrations since most systems do not collect such information across the designated record set in a concise format. The data will not be uniform, thereby causing significant manual work to collect and present it in a "machine-readable format" as defined in the rule. Our concern is that the money to be spent to develop these new systems, divided by the number of requests, will result in a very high cost per request.

There are many disparate systems, disparate data sets, and limited shared audit information between systems. A manual process would be required to collect data from each system, convert it into readable form and then explain it to the individual. Producing a full set of access reports for all designated record sets is unduly burdensome and expensive, especially since large hospitals have dozens to hundreds of DRS systems containing PHI. AHIMA believes that this will take a great deal of time and resources from the covered entity and business associates in processing requests.

Currently, there is no single "fix" that can be applied to each of the systems to combine the data for the access report into a single format. The workflow processes for each of these systems must also be taken into account when collecting the data. Extensive training of the workforce will be required for covered entities and business associates to identify when an individual is requesting an access report. Organization will have to ensure all areas are competently trained for all the entry points included in an access report.

AHIMA's HIM professionals believe that if the request for access reports are limited in number and limited in scope, the 30-day requirement with one 30 day extension should suffice. Limiting the scope by individual, time frame or other factor may allow for time savings in the work processes. AHIMA supports limiting the requests. OCR must be explicit in the right of the covered entity and business associates in the attempt to narrow the request.

***VI. C. How much will it cost covered entities to notify individuals of their new privacy rights?
(76FR31445)***

AHIMA professionals do not feel OCR accurately reflected actual expenses in estimating the cost to revise notices of privacy practices and individuals. There are varying requirements to translate documents into multiple languages, as some areas of the country may have more languages to translate than others. Our members also felt that the time allotted for the attorney review was low. Most attorney reviews would be conducted in the scope of the full notice for privacy practices, not just the updated section. Another cost not taken into account is the cost to update and obtain attorney review every time a new state or federal law is mandated. The privacy notice will have to be updated with each change unless a separate listing is allowed as recommended by AHIMA.

VII. Collection of Information Requirements (76FR31446)

The requirement for the accounting for access is based on a number of significant changes in healthcare, business associates, covered entities, and consumers. Many of the questions related to system changes, workflow changes, and number of requests, to name a few, cannot be fully answered. Requiring access reports across disparate designated record systems only adds to the complexity of determining the impact.

It has been suggested to us that OCR, in conjunction with other HHS agencies, develop a pilot to test the assumptions in this report for access. Such a pilot should also test consumer awareness and education. In short, in addition to not knowing the impact on covered entities and business associates, the burdens will not be known if we cannot determine how the average consumer will or will not request an access report. We believe that such a pilot would benefit all parties and we would be happy to work with the OCR to establish parameters.

If there are additional questions or concerns regarding this response, or other questions regarding HIPAA, HITECH, confidentiality, privacy, or security, please contact me at the address or phone number above, or at dan.rode@ahima.org. In my absence, please contact either Allison Viola, AHIMA's Director of Federal Relations, at the same address and phone, or at allison.viola@ahima.org, or Harry Rhodes, AHIMA's Director of Practice Leadership at (312) 233-1119, or harry.rhodes@ahima.org.

We thank you for your time and consideration of these comments.

Sincerely,

//signed//

Dan Rode, MBA, CHPS, FHFMA
Vice President, Policy and Government Relations

Cc: Allison Viola, MBA, RHIA
Harry Rhodes, MBA, RHIA, CHPS, CPHIMS, FAHIMA AHIMA Membership
Office of the National Coordinator