



May 18, 2010

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

Attention: HITECH Accounting of Disclosures Request for Information

Dear Secretary Sebelius:

The Confidentiality Coalition is pleased to respond to the Request for Information on accounting of disclosures as published in the Federal Register on May 3, 2010. The Confidentiality Coalition is a broad-based group of hospitals, medical teaching colleges, health plans, pharmaceutical companies, medical device manufacturers, biotech firms, employers, health product distributors, pharmacy benefit managers, pharmacies, and patient groups founded to advance effective patient confidentiality protections.

In the Federal Register notice request for information (RFI), OCR provides a series of specific questions to guide commenters' responses. With this in mind, we would like to respond to question numbers one and four, which address the benefits and usefulness of an accounting of disclosures report, as well as provide additional information for the Department to use as it promulgates regulations.

Frequency of Requests

In 2009, the Confidentiality Coalition distributed a survey to its members designed to determine the financial burden that organizations will incur in order to comply with the new accounting of disclosures requirement, as well as help assess the current administrative burden and level of individuals' interest in accounting of disclosures reports for non-routine disclosures. The survey responders consisted of hospitals, integrated health systems, and drug stores, all of which are considered providers under the HIPAA Privacy Rule. In general, survey responses revealed a dearth of requests for an accounting of disclosures report. Specifically, the total number of individuals requesting an accounting of disclosures report since April 2003, when the HIPAA provision to provide an accounting of non-routine disclosures took effect, ranged from a low of zero to a high of 15. In 2008 alone, the number of individuals requesting an accounting of disclosures (AOD) report ranged from a low of zero to a high of three. We have been informed anecdotally from other Confidentiality Coalition members that AOD reports are rarely requested, further emphasizing the survey results.

Benefit and Utility of Accounting of Disclosures Reports

Even in the rare instances where an accounting of disclosures was requested, the resulting report seldom provided the information the requesting individual was seeking. For example, our survey responses indicated that the most common reason for requesting an AOD report involved a family dispute. Such family-related requests often involve a former spouse requesting information regarding a child. It should be noted that this kind of parental access, even under the expanded rule, would not be required to be included in an accounting of disclosures report (CFR 164.528). Other AOD requests received by our member organizations include instances in which the requestor is singularly interested in whether a particular individual has viewed her protected health information (PHI).

Per section 13405(c) of HITECHⁱ, more people may become aware of their right to request an AOD report. However, the experience of our members, as indicated above, shows that even if the numbers of requests increase, the resulting report is unlikely to produce the information that the requestor seeks. On the contrary, a typical AOD report contains an overwhelming amount of granular, non-relevant, technical jargon and codes that are unlikely to be meaningful or useful to the requestor.

Furthermore, to account for the disclosures for treatment, payment, and healthcare operations (TPO), as required by HITECH, the sheer volume of data involved for a single individual makes it an impractical method to identify *in a meaningful manner* where and to whom information has been disclosed. For example, non-employed clinicians at one Coalition delivery system access patient information in just one of the four principal clinical information systems over one million times a month. Additionally, many of our Coalition members are early adopters of electronic health records, and as such, they have many different databases and systems with patient information, both home-grown and vended products. They have systems for radiology images, systems for lab work, systems for clinical care in the hospital setting (which are often different from the systems for clinical care in outpatient clinics and home care settings), systems for patient admitting, systems for patient billing, systems for pharmacy, and so forth. Not all of these systems have the ability to maintain or track disclosures for three years. While most systems currently track additions to a patient record by user, many disclosures that would be necessary under the expanded accounting of disclosures requirement result from simply viewing the record, which is frequently not trackable.

Effective Alternatives

Rather than an accounting of disclosures report, which poses numerous financial and administrative burdens, our members have in place formal privacy investigation processes that are more likely to identify to whom or where information has been disclosed, and thus fulfill the needs of the requesting individual. Our members have stated that patients are highly satisfied with these investigations because the provider has been able to determine whether the patient's privacy was violated, which is generally the underlying motivation for an AOD request. In the event that the investigation reveals a privacy violation, patients have been assured that appropriate disciplinary measures were taken. Indeed, our members have terminated employees for violating patient privacy.

Current Technological Concerns

We also urge that forthcoming regulations on AOD provide additional clarity about what constitutes a reportable disclosure and what "through an EHR" means per HITECH for purposes of accounting of disclosures. We recommend that an EHR be limited to certified EHRs and that

“through the EHR” be defined to mean through the principal clinical data system containing the bulk of the electronic health record.

We also point out that HITECH directed the HHS HIT Policy Committee to make recommendations with respect to “technologies that as part of a qualified EHR allow for an accounting of disclosures made by a covered entity for purposes of treatment, payment, and healthcare operations.” Until such recommendations for technologies that allow for the automatic generation of an AOD report – and not a manual, retrospective review of reams of system output data – are made public by HHS, no information should be required to be collected regarding TPO disclosures. Furthermore, additional requirements should respond specifically to demonstrated patient needs.

The expanded requirements for AOD should not be imposed until technological solutions that allow automatic generation of AOD reports are widely available at a reasonable cost. Currently, we are unaware of any particular technology solution that is capable of automatically generating an AOD report from multiple clinical information systems. Indeed, we are unaware of any technology that automatically distinguishes between a “use” and a “disclosure” as the HIPAA regulations define these terms.

Two-year Extension

Given the concerns listed above, we urge the Secretary to use her discretion to delay the compliance date for these new accounting of disclosures requirements by two years for both existing and new users of electronic health records. Compliance by January 2011 is simply not possible under the current environment given the fact that technological solutions to adequately address this requirement do not exist. As the nation strives to bend the cost curve in health spending, the imposition of any costly new requirements must be well-justified. Any new requirements should not be imposed until the technology needed to comply with these requirements is readily available to all users at a reasonable cost. We also urge the department to consider when and how alternate methods, such as formal privacy inquiries, may be a more direct and efficient method to address the privacy concerns of patients.

The Confidentiality Coalition sincerely appreciates the opportunity to offer its comments with regard to HITECH’s expanded accounting for disclosures requirement. Please do not hesitate to contact Tina Olson Grande at (202) 452-8700 or tgrande@hlc.org if we can be of further assistance.

Sincerely,



Mary R. Grealy
President
Healthcare Leadership Council
On behalf of the Confidentiality Coalition

ⁱ The “American Recovery and Reinvestment Act of 2009” (ARRA, Public Law 111-5).