



Continua
HEALTH ALLIANCE

August 1, 2011

Secretary Kathleen Sebelius
Director Georgina Verdugo
U.S. Department of Health and Human Services
Office for Civil Rights
Attn: HIPAA Privacy Rule Accounting of Disclosures; RIN 0991-AB62
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

RE: RIN 0991-AB62; Comments on HIPAA Privacy Rule Account of Disclosures under the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”)

Dear Secretary Sebelius and Ms. Verdugo:

The more than 230 members of the Continua Health Alliance (“Continua”) thank the Office for Civil Rights (“OCR”) for accepting comments related to the Notice of Proposed Rulemaking for the HIPAA Privacy Rule Accounting of Disclosures under the HITECH Act.¹ Continua is a non-profit, open industry coalition of healthcare, technology, and medical device companies joining together in collaboration to improve the quality of healthcare through the use of technologies such as telehealth, remote patient monitoring (“RPM”), electronic care (“eCare”), mobile health (“mHealth”), and other health information technologies (hereafter referred to collectively as “personal connected healthcare”).² Our members include both “covered entities” and “business associates,” as defined in regulations implementing HIPAA.³

Below are Continua’s comments on the portions of the proposed rule relating to changes in an individual’s right to an accounting of disclosures and an individuals’ right to an access report.

¹ HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act, 76 Fed. Reg. 31426 (May 31, 2011).

² “Telehealth” is defined in statute, and currently it includes professional consultations, office visits, and additional services. 42 U.S.C. § 1395m(m)(4)(F). Though not defined in statutes or regulations, “RPM” is recognized widely to mean wireless devices and sensors that monitor patients’ conditions from home or someplace other than health care providers’ offices and report the data to health care providers and/or EHR systems, permitting patients to be full partners in their care. “eCare” and “mHealth” appear as explained terms in the March 2010 Federal Communications Commission document, “National Broadband Plan: Connecting America,” available at <http://www.broadband.gov/download-plan/>. “eCare” is the electronic exchange of information—data, images and video—to aid in the practice of medicine and advanced analytics, encompassing technologies that enable video consultation, remote monitoring and image transmission (“store-and-forward”) over fixed or mobile networks. “mHealth” is the use of mobile networks and devices in supporting e-Care, leveraging health-focused applications on general-purpose tools such as smart-phones and Short Message Service (SMS) messaging to drive active health participation by consumers and clinicians.

³ See 45 C.F.R. § 160.103.

A. Accounting

OCR proposes to modify the existing requirements for disclosure accounting, and Continua offers the following comment on the specific proposed modifications.

Limiting accounting to disclosures of information in designated record sets: Continua supports OCR's proposal to limit the accounting provision to only that protected health information ("PHI") contained in a designated record set.⁴ We agree that information in a designated record set – that information used to make decisions about individuals – is the most relevant to an individual who seeks an accounting of disclosures.

Accounting time frame: We also support OCR's proposal that covered entities and business associates would have to account for disclosures over the previous three years, instead of the six year period currently specified in regulations.⁵ Given the complexity of the HIPAA regulations in general, and the volume of PHI with which some of Continua's members deal day-to-day, it makes sense to simplify this portion of the Privacy Rule by aligning the time period with other requirements, and it reduces the burden on covered entities and business associates alike who must maintain information on disclosures. Continua also supports the reduction in the time frame for which a covered entity or business associate must maintain documentation in order to provide an accounting of disclosures, from six years to three years.⁶

Exempting disclosures contained in a breach notification: We support OCR's proposal to exempt from the accounting requirement those impermissible disclosures about which a covered entity, either directly or through a business associate, already has provided a breach notice to an individual.⁷ It is administratively burdensome for a covered entity or a business associate to have to respond to accounting requests if it already has taken the affirmative step of providing a breach notice, because the breach notification generally serves the same purpose as the accounting.

The content of an accounting: Continua supports the proposal to expand the ways for describing the date or time period a disclosure occurred.⁸ Occasionally, it is not possible to know the exact date of a disclosure or multiple disclosures, and so it is helpful to be able to state a date, a date range, or a description of a date in relationship to other events. The purpose of providing the date to the individual seeking the accounting still will be met: learning when an individual or entity obtained PHI about the individual.

Continua also strongly supports standardizing the practice of covered entities providing an individual with an option to limit the accounting to a particular time period, type of disclosure, recipient, or organization disclosing the PHI, as in proposed 45 C.F.R. § 164.528(a)(2)(ii), because it reduces the administrative burden on both covered entities

⁴ 76 Fed. Reg. 31,430

⁵ *Id.*

⁶ *Id.* at 31,436.

⁷ *Id.* at 31,431.

⁸ *Id.* at 31,434.

and business associates, and it permits an individual to receive only the information that matters most to him or her.

In the same way, Continua supports permitting covered entities to require individuals to make accounting requests in writing. However, it encourages OCR to alter proposed 45 C.F.R. § 164.528(a)(3)(iv) to permit a covered entity to require an individual to use a form provided by the covered entity. A form would serve at least three purposes: 1) it would be another opportunity for a covered entity to encourage an individual to limit an accounting request to only that information and/or time period that is most important to the individual, 2) it would decrease the administrative burden for covered entities who receive written accounting requests to receive them in a single format, and 3) it would ensure that an individual provides all pertinent information so that a covered entity may respond fully to the request. Although OCR “encourage[s] covered entities to create forms for individuals to request an accounting that inform individuals of the information that will be included and the allow individuals to narrow the request,” it is not clear from the rule as written that a covered entity may require such a form, and this should be explicit in the rule.

Responding to an accounting request: Continua opposes shortening the time frame for responding to an accounting from to 30 days from the current allowable 60 days.⁹ While our members endeavor to respond to accounting requests as quickly as possible, it oftentimes is not feasible to collect and organize information about disclosures made by a covered entity and by and to all business associates in such a short time, especially where a covered entity has a complex business and has many business associates. This is especially true when an individual has not accepted the suggestion to limit an accounting request to a particular period of time or organization, for instance. OCR recognizes that there are times when it is not possible to respond fully to an accounting request within 30 days, which is why it proposes the possibility of a 30 day extension. However, that requires an additional step on the part of the covered entity or business associate who received the request – notifying the individual of the reason for the delay – and we are unaware what purpose it would serve to inform an individual about why the delay has occurred. We believe that most individuals understand the complexity of accounting for disclosures of their PHI, and we think the marginal benefit to individuals of a shorter 30-day time frame is outweighed significantly by the burden to covered entities and business associates.

B. Access Report

In addition to the right to an accounting of disclosures, OCR proposes to provide individuals with a separate right to receive an access report that indicates who has accessed the individual’s designated record set information. Continua offers the following comments on OCR’s proposals.

⁹ *Id.* at 31,435.

All electronic PHI in a designated record set: Continua applauds the OCR for recognizing the fluid nature of health information technology in its proposal to broaden the information that must be included in an access report beyond information contained in an EHR to “all electronic PHI in a designated record set.”¹⁰ It is important to realize, as OCR notes, that “as health information technology advances, the concept of what constitutes an EHR is in a state of flux.”¹¹ Continua’s members develop and produce health information technology that is at the cutting edge of telehealth and other personal connected healthcare, and some of the technologies are recognized and incorporated in certain health care payment systems but not others. However, as we fully expect that all technologies eventually will be integrated into health care delivery and payment systems as standard elements, it is preferable to apply the same requirements and standards to all technologies that capture or transmit electronic PHI. This approach also yields greater clarity for covered entities and business associates unsure of what constitutes an “EHR.”

Content of an access report: We appreciate that OCR recognizes that it oftentimes is not possible to know the name of the person who has accessed information.¹² This is especially true when the access was from outside the covered entity or when data is exchanged with another system within an organization. We also appreciate that the proposed rule does not require an access report to include the address of the person who accessed the information. Not only does the burden of collecting that information outweigh the benefit to an individual requesting an access report, but it also is intrusive to employees of covered entities and business associates who work with PHI day in and day out and who simply are doing their jobs when they create, delete, access, or modify electronic PHI. Finally, we support the decision not to require an access report to include the purpose of the access, since this information oftentimes is unknowable.

Limiting the scope of an access report: As with the accounting request, Continua strongly supports standardizing the practice of covered entities providing an individual with an option to limit an access report to a particular time period, individual, or organization accessing the PHI, as in proposed 45 C.F.R. § 164.528(b)(2)(ii), because it reduces the administrative burden on both covered entities and business associates, and it permits an individual to receive only the information that matters most to him or her.

For the reasons set forth above in the section on accounting, Continua supports the proposal to permit covered entities to require an access report request to be in writing, and it encourages OCR also to permit covered entities to require that such a request be on the covered entity’s form.

Responding to the access report request: Continua disagrees with OCR’s proposal to permit covered entities just 30 days to produce an access report.¹³ As OCR recognizes earlier in the preamble, “a covered entity will usually have electronic designated record set information in multiple systems which each maintain separate access logs” and that “data from each access log will be gathered and aggregated to generate a single access

¹⁰ *Id.* at 31,437.

¹¹ *Id.*

¹² *Id.* at 31,438.

¹³ *Id.* at 31,440.

report (including data from business associates' systems)."¹⁴ It is not realistic to expect a covered entity to be able to aggregate and construct an access report from multiple systems and potentially multiple organizations' systems within that time frame.

C. General Comments

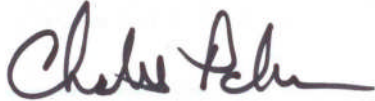
The entity responding to a request: Continua believes that, under certain circumstances, covered entities should have the option of directing an individual to a business associate to request an accounting of disclosures or an access report. The covered entity should be able to do so if it has a reasonable belief that the business associate can respond accurately and timely to the request and if the covered entity and the business associate have a written agreement (either as a part of the business associate agreement or separately) that sets forth the procedure for responding to such a request. If a covered entity does not have such a written arrangement with a business associate, it ought to remain responsible for responding to requests. Covered entities and their business associates should be permitted to determine which entity is best suited to respond to the various types of accounting and access report requests and to form contractual agreements accordingly. (The same sort of agreement ought to be permissible between covered entities when more than one covered entity may have to respond to an individual's request.) Such an arrangement would protect the requesting individual's interests adequately, while paying heed to the burden on covered entities and their business associates.

The administrative burden of integrating the proposed changes: OCR did not adequately capture the full cost to covered entities and business associates of the proposed changes to the HIPAA Privacy Rule. Virtually all business associate agreements would need to be amended, requiring a commitment of time and legal fees on the part of all covered entities and business associates. Additionally, each organization's operating procedures and training would need to be amended to take into account changes in how to respond to a request, what information to include, and the speed with which the organization must respond to each request, among other things. Finally, some organizations will need to purchase new information systems and/or upgrade existing systems to meet the regulation's requirements, the expenses for which it will have to absorb or pass on to consumers. OCR failed to consider all of the burdens to covered entities and business associates of integrating the proposed changes into organizational work flows and operating procedures.

¹⁴ *Id.* at 31,436.

Continua appreciates the opportunity to comment on the Proposed Rule and hopes that the OCR will incorporate Continua's suggestions in the final rule. Thank you for your consideration of our recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "Chuck Parker". The signature is fluid and cursive, with a long horizontal stroke at the end.

Chuck Parker
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