

June 15, 2011

ACCOUNTING OF DISCLOSURES UNDER HITECH: PROPOSED RULE

AT A GLANCE

The Issue:

The Department of Health and Human Services' (HHS) Office for Civil Rights issued in the May 31 *Federal Register* a [proposed rule](#) to modify the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) privacy rule's provisions related to accounting of disclosures. HHS' proposal would create two separate rights for individuals: a revised right to an accounting of disclosure of the individual's protected health information (PHI) and a new right to a report identifying who has electronically accessed the individual's PHI. In part, these proposed modifications would implement the *Health Information Technology for Economic and Clinical Health Act's* (HITECH) specific mandate for accounting of disclosures of PHI to carry out treatment, payment and health care operations made through an electronic health record. However, HHS also is using its more general authority under HIPAA to propose modifications to ensure that individuals receive the information about disclosures that is of most interest to them.

This advisory examines the specific changes included in HHS' proposed rule. Comments on the proposed rule are due by August 1.

Our Take:

For hospitals and other covered entities, the proposed changes will certainly continue – and likely increase – the heavy administrative burdens involved in producing individualized, patient-friendly accounting of disclosures and the new required reports on electronic access. Capturing large volumes of raw data, even if it is done automatically as part of a particular electronic system's audit log, does not equate directly to the production of reports that can be easily read and understood by an individual patient. Moreover, it does not ensure patients receive the information they value most about whether there was a specific privacy violation relating to that individual patient's PHI and what appropriate disciplinary and other measures a covered entity has taken to ensure that those violations were properly addressed and do not recur.

What You Can Do:

- ✓ Share this advisory with your legal counsel, privacy and security officers, and other members of the HIPAA implementation team.
- ✓ Ensure that your organization has clearly identified and documented what qualifies as designated records sets of the organization and its business associates, including electronic and paper record sets.
- ✓ Evaluate the current capabilities of your organization's and its business associates' electronic systems to collect, generate and store necessary audit log information, including the organization's ability to access and analyze information from its own multiple electronic systems and those of all the organization's business associates.
- ✓ Consider submitting comments on the proposed rule that focus on technical capabilities and limitations of the organization's electronic information systems, administrative and resources burdens of reporting, and experiences with patient requests and the perceived value to patients of the information requested.
- ✓ Watch for an AHA model comment you can use as you draft and submit your own comments by August 1.

Further Questions:

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BACKGROUND

The Office for Civil Rights of the Department of Health and Human Services (HHS) issued in the May 31 *Federal Register* a [proposed rule](#) to modify the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) privacy rule's provisions related to accounting of disclosures. HHS specifically proposes in this rule to create two separate rights for individuals: a revised right to request and receive from a covered entity an accounting of disclosure of the individual's protected health information (PHI) and a new right to request and receive from a covered entity a report identifying who has electronically accessed the individual's PHI.

These modifications are proposed, in part, to implement the specific mandate in the *Health Information Technology for Economic and Clinical Health Act* (HITECH) for accounting of disclosures of PHI to carry out treatment, payment and health care operations if the disclosures are through an electronic health record (EHR). However, HHS points out that it also is using its more general authority under HIPAA to make additional modifications that would ensure that individuals receive the information about disclosures that is of most interest to them and to improve the general workability and effectiveness of the rule's accounting provisions.

This *Legal Advisory* examines the specific changes proposed in this rulemaking. Comments on the proposed rule are due to HHS by August 1.

AS IT STANDS

Proposed Revisions to the Accounting of Disclosures of PHI

HHS proposes a somewhat more limited right to an accounting. Currently, an individual's right to an accounting covers certain disclosures of PHI regardless of the location of the PHI. The proposed rule would limit the individual's right to request and receive from a covered entity an accounting of disclosures to only certain disclosures of information *in a designated record set* of the covered entity and its business associates. Designated record set is defined in the current

HIPAA privacy rule at Sec. 164.501 to mean generally the medical and health care payment records maintained by or for a covered entity, and other records used by or for the covered entity to make decisions about individuals. As HHS suggests, understanding disclosures of such information, which is at the core of treatment and payment decisions about an individual, is what most concerns patients.

HHS believes that covered entities should know already which systems qualify as designated record sets because the current HIPAA regulations require that covered entities document the designated record sets that are subject to the individual's right to access and to retain that documentation. In addition, covered entities already are required under the current regulations to require in the business associate agreement that business associates make available information required to provide an accounting of disclosures and to include disclosures to and by business associates in the accounting of disclosures provided to an individual. As a result, HHS includes an explicit reference in the proposed rule to require that the covered entity include business associates' disclosures of designated record set information in the accounting of disclosures. However, the proposed rule would *not* require accounting for any disclosures by business associates of information outside of a designated record set.

HHS specifically requests comments on the proposal to limit the accounting to disclosure of information in the designated record set, including whether there are unintended consequences for covered entities or an individual's privacy interests.

Scope of the right to an accounting of disclosures. HHS suggests that it has simplified and made the accounting of disclosure provision easier to understand in the proposed rule by explicitly listing the types of disclosures that would be subject to the accounting in contrast to the current rule's approach, which makes disclosures generally subject to the accounting obligation and then lists specifically those disclosures that are exempt. In fact, the proposed provision includes a combination of included and excluded information, identifying that a covered entity must include disclosures:

- Not permitted by the HIPAA privacy rule, *unless* the individual already has been informed of the impermissible disclosure in a required breach notice letter provided in accordance with current federal breach notification requirements (Sec. 164.404).
- For public health activities, *unless* the disclosure is to report child abuse or neglect (Sec. 164.512(b)).
- For judicial and administrative proceedings (Sec. 164.512(e)).
- For law enforcement purposes (Sec. 164.512(f)).
- To avert a serious threat to health or safety (Sec. 164.512(j)).

- For military and veterans activities, the Department of State’s medical suitability determinations and government programs providing public benefits (Secs. 164.512(k)(1), (4) and (6)).
- For worker’s compensation (Sec. 164.512(l)).

The proposed provision additionally specifies that the covered entity would *not* be required to account for disclosures that are “required by law” (Sec. 164.512(a)) – not merely authorized by law – including any disclosures for a purpose that would otherwise be subject to the accounting *unless* that particular disclosure is for judicial and administrative proceedings (Sec. 164.512(e)) or for law enforcement purposes (Sec. 164.512(f)). HHS explains that it is proposing to exclude most disclosures that are required by law because they “are often population based rather than related to a specific individual, because they often reflect a determination by a state legislature or other government body rather than a discretionary decision of a covered entity or business associate, and because we believe it is reasonable to assume that individuals are aware that their health information will be disclosed where mandated by law.” Further, the privacy rule currently ensures that individuals are generally informed through a covered entity’s Notice of Privacy Practices that a covered entity may disclose an individual’s PHI when required to do so by other law. Many previous comments to HHS indicated that accounting for these nondiscretionary disclosures represents a significant administrative burden on covered entities; and consequently, the agency proposes that such disclosures need not be included in an accounting in order to lessen this administrative burden. In contrast, because disclosures for law enforcement purposes and judicial and administrative proceedings directly implicate an individual’s legal and/or personal interests, HHS believes the individual should have a right to learn of such disclosures.

In the preamble, HHS clarifies that its proposed new regulatory approach for accounting of disclosures would continue to exclude from the accounting obligation, disclosures:

- To individuals of their own PHI (Sec. 164.502).
- Incident to an otherwise permitted or required disclosure (Sec. 164.502).
- Under authorization (Sec. 164.508).
- For the facility directory or to persons involved in the individual’s care or other notification purposes (Sec. 164.510).
- For national security or intelligence purposes (Sec. 164.512(k)(2)).
- To correctional institutions or in law enforcement custodial situations (Sec. 164.512(k)(5)).
- As part of a limited data set (Sec. 164.514(e)).
- Occurring prior to the compliance date for the covered entity.

The revised right to an accounting would cover disclosures of both electronic and paper information (although now limited under the proposed rule to a designated record set) as does the current rule’s obligations. Under the proposed rule

however, the right to receive the accounting of disclosures would encompass only disclosures made in the three years preceding the date of the individual's request in contrast to the current requirement, which covers the preceding six years. *HHS requests comments on whether there is a need for accounting of disclosures beyond the proposed three-year limit.*

HHS also requests comment on whether the agency should exempt certain additional categories of disclosures that currently are subject to the accounting obligation and the rationale that the agency advances for such additional exclusions, including:

- **Disclosures related to reports of adult abuse, neglect or domestic violence** (Sec. 164.512(c)). HHS believes that accounting for such disclosures might endanger the reporter of the abuse. HHS also notes that in most cases, the individual will be affirmatively notified of the disclosure by the covered entity because the current HIPAA privacy rule in Sec. 164.512(c)(2) actually requires the covered entity to promptly inform the individual that such a report has been or will be made unless doing so may endanger the individual.
- **Disclosures for research**, including research where an institutional review board (IRB) or privacy board has waived the requirement to obtain individual authorization for the disclosure (Sec. 164.512(i)). As HHS clarifies, the agency is considering in the proposed rule exempting research disclosures from inclusion in the accounting even through a listing of protocols, which the current rule permits covered entities to use to simplify the accounting for studies involving 50 or more individuals. According to HHS, individuals would continue to be informed through the Notice of Privacy Practices that their PHI may be used or disclosed for research and the privacy rule itself limits the circumstances for research disclosures. HHS explains that it is considering a research exemption because it continues to hear about the administrative burdens and the potentially chilling effect of the accounting of disclosures requirement on human subjects research. *However, the agency requests comments about the value to individuals of the current research-related accounting obligations, including the most important or valuable element of the accounting, the number of protocols typically included in the simplified protocol listing, the nature and number of smaller research studies that require the more detailed reporting, the burdens for researchers and covered entities to provide requested research accounting and alternative, less burdensome ways to provide information to individuals about the covered entity's research disclosures.*
- **Disclosures for health care oversight activities** (Sec. 164.512(d)). HHS suggests that such disclosures primarily are population-based or event-triggered and relate more to the covered entity than an individual

whose information is disclosed. Additionally, such disclosures often are routine, to a government and required by law. As a result, HHS does not believe that “the potential burden on a covered entity or business associate to account for what may be voluminous disclosures . . . is balanced by what is likely not a strong interest . . . of individuals to learn of such disclosures.” *However, HHS requests comments on these assumptions.*

- **Disclosures about decedents to coroners, medical examiners and funeral directors** (Sec. 164.512(g)). HHS suggests these disclosures are relatively routine, expected by individuals and do not raise significant privacy concerns.
- **Disclosures about decedents for cadaveric organ, eye or tissue donation** (Sec. 164.512(h)). As HHS explains, the current privacy rule already limits the circumstances and nature of any such permissible disclosure. Further, HHS anticipates that families will be involved in the decision-making related to the donation.

The agency states that it will, as it works to produce a final rule, revisit these exclusions based on the public comments received.

HHS also requests comments about a number of additional issues raised implicitly by the proposed provision with its explicit list of disclosures to which the accounting obligation would apply, specifically whether:

- Including in the accounting of disclosures information that already is provided to the individual in a breach notification letter creates burdens to covered entities and/or benefits for individuals requesting the accounting.
- Whether, without being too complex and confusing for covered entities and individuals, the rule should specify, as HHS now proposes for reports of child abuse or neglect, an explicit exemption from the accounting of disclosures obligation for additional categories of public health disclosures because such disclosures “may be of limited interest to individuals and/or because accounting for such disclosure may adversely affect certain population-based public health activities, such as active surveillance programs.”

Content and format of the accounting. HHS proposes to retain the current elements of the accounting of disclosures with some minor modifications. Under the proposed rule, the accounting would now include:

- **Date of the disclosure, if known, or the approximate date or period of time for the disclosure if the specific date is not known.** The approximate date must include, at a minimum, a month and year (e.g., December 2013) or a description of when the disclosure occurred that

would enable an individual to “readily determine the month and year” (e.g., between January 1 and January 31, 2013).

For multiple disclosures to the same person or entity for the same purpose, the proposed rule would no longer require the exact start and end date for the disclosures. Rather, the approximate period of time would be sufficient (e.g., for numerous disclosures, “December 2013 through August 2014,” or “monthly between December 2013 and present”). HHS explicitly cautions that a “time period of multiple months is permitted for multiple disclosures to the same recipient for the same purpose, but not for a single disclosure.” Therefore, three disclosures between January and May 2013 could be described as “between January and May 2013,” but a single disclosure in February 2013 may not be described as “between January and May 2013.”

HHS also clarifies that the date of disclosure may be descriptive, rather than a specific date. Therefore, the accounting may state, for example, that a disclosure to a public health authority was “within 15 days of discharge” or “the fifth day of the month following discharge.”

- **Name of the entity or natural person who received the disclosure and, if known, address of the recipient.** This proposal generally tracks the current requirement, but HHS proposes an exception to address concerns that providing the name of a natural person might unnecessarily disclose the PHI of an individual by, for example, demonstrating that the recipient of the disclosure also is a patient of the provider and mistakenly received an appointment reminder intended for another patient. In this situation, the proposed rule would permit using “another patient” instead of the recipient’s actual name and address in the accounting of disclosures.
- **Brief description of the PHI disclosed.** HHS proposes a slight revision to the existing requirement to reflect that the accounting is required to provide information about *only the types of PHI* that were disclosed. Therefore, under the proposed rule, covered entities would be required to include a “brief description of the type of protected health information disclosed” rather than a “brief description of the protected health information disclosed,” as the current requirement reads.
- **Brief statement of the purpose of the disclosure.** HHS also proposed a slight revision to the existing requirement to make clear that only a minimum description is required *if* it “reasonably informs the individual of the purpose” of the disclosure. Therefore, under the proposed rule, covered entities would be required to include a “brief statement of the purpose of disclosure” rather than a “brief description of the purpose” as the current requirement reads. Descriptions such as “for public health” or

“in response to law enforcement request” would be sufficient under the proposed rule.

However, HHS retains the regulatory language that covered entities may, in lieu of the description, provide a copy of a written request for the disclosure. HHS explicitly states that covered entities are *encouraged* to provide a copy of such written request when it provides more information about the purpose of the disclosure than the brief statement. According to HHS, a copy of the written request will “better inform the individual of the circumstances surrounding the disclosure.”

Under the proposed rule, covered entities would be required to offer individuals the option to limit the accounting to a particular timeframe, type of disclosure or recipient even though the individual’s right to the accounting includes all disclosures occurring within the three years preceding the request. As HHS states, such options are “in the best interests of both the individual and the covered entity.” Covered entities also would be permitted to offer individuals other options to limit an accounting of disclosures (e.g., disclosures by only the covered entity or by a particular business associate). HHS does not plan to include specific regulatory language about other options because the agency anticipates that “it will be less likely that individuals will be interested in limiting their accounting requests in this way.” However, HHS states that the lack of regulatory language “should not be interpreted as prohibiting covered entities from offering individuals the option to limit their accounting request by organization.”

Imposition of New Obligations to Provide Access Reports

Under the proposed rule, an individual has a new right to request and receive *from a covered entity* a written report that indicates who has *accessed* the individual’s PHI in *any* electronic designated records sets the *covered entity or its business associates maintain*.

HHS believes that the proposed right to an access report will require covered entities and their business associates to make only minimal, if any, changes to existing information systems. Compliance with the current HIPAA security rule and business associate agreements already require that covered entities and business associates log the information necessary for an access report and from such logs covered entities should be able to generate an access report. Further, HHS does not believe that aggregating relevant data into a single access report, even if the data resides in a number of distinct systems that maintain separate access logs, will be a significant burden for covered entities. Rather, HHS states:

[W]e believe that this administrative burden is reasonable in light of the interests of individuals in learning who has accessed their protected health information. Additionally, the burden of generating

access reports will be directly proportionate to the interests of individuals; if few individuals request access reports, then covered entities will rarely need to undertake the burden of generating an access report.

However, HHS requests comment on the conclusions it expresses above.

Scope of the right to an access report. The right to the access report extends to information about access for up to *three years prior* to the date of the request. The right pertains solely to electronic information; it does not cover access to paper records.

HHS describes the access report as a “document that a system administrator or other appropriate person generates from the access log in a format that is understandable to the individual.” The access log is the “raw data that an electronic system containing PHI collects each time a user – defined in the HIPAA security rule at Sec. 164.304 as “a person or entity with authorized access” – accesses information. HHS understands that a covered entity will usually have designated record sets in multiple electronic systems that each maintain and generate separate access logs. Consequently, HHS makes clear that the agency’s expectation under this proposed revision is that data from each access log, including data from business associates’ systems, will be aggregated and combined into a single access report. Note that HHS does not adopt in this proposed rule the currently allowable option for covered entities to comply with the accounting of disclosures requirement by providing an accounting of disclosures made by the covered entity and a list of all business associates with their respective contact information to enable the individual to contact the business associates directly to request an accounting of disclosures by the business associates. Under the proposed rule, the covered entity is specifically responsible for including in the accounting disclosures made by all its business associates as well as those disclosures made directly by the covered entity.

Content and format of the access report. In the access report, the covered entity must include:

- **Date and time of access.** Noting that access logs frequently include both the start and end time of the access, HHS indicates that the intent of this content specification is for the covered entity to include the start time in the access report, but that they are free also to include the end time, when available.
- **Name of natural person, if available, or otherwise the name of the entity accessing the electronic designated record set.** HHS notes that while some access logs may rely on a User ID instead of the first and last name of an individual user, the expectation is that the covered entity easily can – and will – match the User ID to the user’s first and last name

for inclusion into the access report, although HHS does not care whether the covered entity uses an automated or manual approach in order to do that matching.

Because an access log in some circumstances may only capture the name of the entity, not the identity of particular persons, receiving information (e.g., when an EHR exchanges information with an organization outside of the covered entity), it is sufficient under the proposed rule to include in the access report the name of the outside entity, rather than a specific individual.

HHS also recognizes that an organization's electronic systems may exchange data with each other. In such circumstances, the proposed rule would permit the access report to identify the access by the name of the covered entity to reflect that the individual's information was accessed by one of the covered entity's own systems. However, to the extent that the covered entity is able to provide a description of the particular system that is accessing the information, HHS specifically encourages the inclusion of the more detailed information. *Recognizing that the burden of providing identifying information about internal systems might significantly outweigh any benefits to individuals in knowing details about the internal exchange, HHS specifically requests comments about:*

- *Interest of individuals in learning about such internal exchanges; and*
 - *Burdens associated with a covered entity's provision of information about internal systems.*
-
- **Description of the information accessed, if available.** HHS recognizes that only some access logs may capture information about what PHI is accessed; and, consequently, the agency does not anticipate that any electronic information systems will be modified to collect such information. Additionally, because the access report may reflect information from different systems' logs, HHS understands that access reports may include some entries that identify what information was accessed while other entries will be left blank. *HHS requests comments on:*
 - *Availability of information about what PHI is accessed in current access logs;*
 - *Importance of the particular information to individual requesting an access report; and*
 - *Administration burden for covered entities to include a description of what information was accessed in the report.*
-
- **Description of the action of the user, if available.** HHS' proposal would require only a general description of the user's action, such as whether the user created, modified, accessed, printed or deleted

information. It is not intended to require that the report provide a description of what ultimate use or disclosure was made with the accessed information or to whom the user provided such information (e.g., the report should not indicate that the user provided a copy of the patient's record to law enforcement).

In this rule, HHS has *not* proposed that covered entities be required to include in the access report:

- Address information that indicates where the access occurred;
- The description of the purpose of the access; or
- The ultimate recipient of the PHI electronically accessed, *unless* the recipient is a natural person or entity with the direct electronic access.

As HHS explains, in each case the burden on covered entities and business associates in providing this information in relation to each access significantly outweighs the benefit to individuals of learning such information. *HHS nevertheless requests comments on its decision to exclude such information from the access report.*

Under the proposed rule, covered entities would be required to offer the option to limit the access report to a specific date, time period or specific person who accessed the individual's information. An individual could request that the report, for example, be limited to whether a particular family member or neighbor accessed the information within the two months previous to the request for the report. HHS also is recommending – but would not require – that covered entities offer the option to limit the access report to access by specific organizations (e.g., the covered entity only or a particular business associate of the covered entity).

Covered entities also would be required to provide the required information so that it is reasonably understandable by the individual without an external aid. Nevertheless, the proposed rule would not require that the report include summary information or any additional content, such as information on the role of each person who accesses the PHI. HHS provides the following example of a report entry formatted to be understandable to the individual:

Date	Time of Access	Name of User	Action
10/10/2013	02:30 p.m.	John, Andrew	Viewed

On the other hand, the following example is *not* in a format understandable to the individual because it remains coded and would require the use of an external decoding guide:

201310101430JOHNANDREW3

Other Implementation Specifications Applicable to Accounting of Disclosures and Access Reports

Permissible to require written requests. The proposed rule would permit covered entities to require that individuals submit written requests for an accounting of disclosures or an access report *as long as* the covered entity informs individuals of the requirement. In the preamble, HHS states that it *encourages* covered entities to develop forms for individuals to use to request an accounting or an access report. Forms can include ways to narrow the scope of the request based on the individual's particular interests.

Requirements related to timeliness, format and fees for report provision. The proposed rule includes the same standard for timely provision of both the accounting of disclosures and for the access report. A covered entity would have 30 days to provide the accounting of disclosures or the access report, including information from its business associates. The covered entity may use a *one-time only*, 30-day extension of the time where necessary, *as long as* the covered entity provides the individual with a written statement explaining the reason for the delay and identifying the date by which it will provide the accounting of disclosures or the access report.

Because HHS specifically plans to reduce the timeframe for providing the accounting of disclosures from 60 days under the current rule to 30 days with the proposed rule, the agency requests comments on the benefits to individuals and the burdens for covered entities of the new timeframes for provision of the accounting, including how long covered entities have needed to collect the information necessary (including information from business associates) for an accounting and to generate the accounting.

HHS proposes to retain the requirement that covered entities delay the provision of an accounting of disclosures if a law enforcement official informs the covered entity that providing an accounting of disclosures to law enforcement would be reasonably likely to impede an ongoing law enforcement investigation. Under the proposed rule, the law enforcement delay pertains solely to the accounting of disclosures obligation; it does not affect the obligation to provide an access report.

If the request for the law enforcement delay is in writing and specifies the time required for the delay, the covered entity must delay the accounting for the specified time period. If the request for delay is oral, the covered entity must document the request, including the identity of the official making it, and delay the accounting for no longer than 30 days from the date of the request for the delay unless a subsequent written request with a specific date is received. A request for delay by law enforcement is not subject to challenge. However, under the proposed rule, a covered entity would still have to account for all other disclosures when law enforcement requests a delay for all or particular

disclosures to law enforcement; and the covered entity would be required to supplement the accounting with information about the law enforcement disclosures upon expiration of the requested delay.

HHS proposes to eliminate the accounting delay for health oversight investigations since disclosures for health oversight activities will no longer be subject to the accounting requirements under the proposed rule.

Covered entities also would be required to produce the accounting of disclosures and the access report in the machine readable or other electronic form (e.g., compatible with a particular software application) that the individual requests, *if the covered entity can readily produce these reports in that form*. HHS proposes that machine readable data is “digital information stored in a standard format enabling the information to be processed and analyzed by computer.” This would include, for example, providing the report in MS Word or Excel, text, HTML or text-based PDF formats. *HHS specifically requests comment on the ability of covered entities to provide access reports in machine readable or other electronic formats.*

If the covered entity cannot readily produce the accounting of disclosures in the form requested by the individual, the covered entity may provide a hard copy or work with the individual to determine if another form is acceptable. The proposed rule does not require that the accounting be provided in electronic form when it cannot be readily produced in such form, because “generating an accounting is still a very manual process and the accounting provisions applies to both electronic and paper records.” However, HHS states that “where covered entities are able to do so (and the individual has not specifically requested a paper copy) we strongly encourage them to provide the individual with a machine readable or other electronic copy of the accounting.” *HHS also requests comment on the burdens associated with providing electronic formats as requested by individuals, machine readable or otherwise.*

If the covered entity cannot readily produce the access report in the form the individual requests, the covered entity may use an agreed-upon readable electronic form. When an individual does not agree to accept the alternative readable electronic form, the covered entity may provide a readable hard copy. If the individual requests a hard copy form, the covered entity would be required to produce the report in a readable hard copy form. Where an individual asks for an electronic copy in an unencrypted format or a form that is not password protected, HHS indicates that the covered entity should provide the electronic copy without such protections. HHS states that the covered entity would not be responsible or liable for the information *once it is in the individual’s possession*.

Under the proposed rule, a covered entity may not charge for the first accounting of disclosures or access report an individual requests in any 12-month period. However, a covered entity would be permitted to charge a “reasonable, cost-

based amount” (including the reasonable costs of including information from business associates) for each additional accounting of disclosures or access report requested within the same 12-month period. The proposed rule would require that covered entities inform an individual at the time of the first request that all subsequent requests may require payment of a fee. Additionally, the proposed rule would require that the covered entity explain the fee for the subsequent request at the time the individual makes the subsequent request and to offer the individual the opportunity to withdraw the subsequent request or modify its scope to avoid or reduce the costs associated with producing the accounting or access report.

Required documentation and retention period. The proposed rule includes the same documentation standard for both the accounting of disclosures and the access report. A covered entity or business associate would be required to retain:

- Documentation necessary to produce the accounting of disclosures and the access report (e.g., the access log) for *three* years.
- Copies of the accounting of disclosures or the access report provided to the individual for *six* years.
- Designation of who is responsible for handling accounting requests and the persons or offices responsible receiving and processing requests for access reports for *six years from the last date the designation was in effect*.

Treatment of Patient Safety Work Product

Under the proposed rule, a covered entity *shall exclude* from accounting of disclosures and access reports any information that meets the definition of “patient safety work product” (defined in federal regulations at 42 CFR Sec. 3.20). Generally, patient safety work product is any data, reports, records, memoranda, analyses (such as root cause analyses) or written or oral statements which could improve patient safety, health care quality or health care outcomes and which a provider assembles or develops and reports to a patient safety organization (PSO). *The Patient Safety and Quality Improvement Act of 2005* protects the confidentiality of patient safety work product and recognizes a legally enforceable right against its compelled disclosure. These protections extend to anything that identifies even the fact of reporting pursuant to a patient safety evaluation system, including the date the information entered the patient safety evaluation system. HHS states in the proposed rule’s preamble, “It is not our intention to interfere with those protections.” Therefore, the proposed rule *would require* that all information related to any patient safety work product be excluded from the accounting of disclosures and an access report.

Revisions to the Notice of Privacy Practices

The proposed rule would require that a covered entity's Notice of Privacy Practices ("Notice") also inform individuals of their new right to receive an access report in addition to the right to receive an accounting of disclosures. This proposed new provision requires, according to HHS, a "material change" in the Notice; and HHS reminds covered entities that under current HIPAA requirements they are obligated to "promptly revise and distribute" their Notices when there is a material change. Health care providers with a direct patient relationship currently must, as of the effective date of the revision to the Notice, promptly post the Notice at any physical service delivery site, make copies available at the site for individuals to take with them, and provide the Notice when an individual requests it. Under the current requirements, health plans must distribute the Notice to plan members within 60 days of the revision, although HHS is considering revisions to this requirement in the final rule it will issue to implement the HITECH changes to the HIPAA privacy, security and enforcement rules. Any changes included in that final rule, if any, also would apply to the accounting of disclosures and the access report obligations.

Given the dates for compliance with the access report requirement contemplated by the proposed rule and discussed in the next section of this advisory, hospitals and other covered entities would need to revise their Notices by the earliest compliance date applicable to any of their designated record set systems. Effectively, this means:

- January 1, 2013 for a hospital or other covered entity that *acquired all* of its designated record set systems *after January 1, 2009*.
- January 1, 2014 for a hospital or other covered entity that *acquired all* of its designated record set systems *on or before January 1, 2009*.
- January 1, 2013 for any hospital or other covered entity that *acquired some* of its designated record set systems *on or before January 1, 2009 and other systems after January 1, 2009*.

Deadlines for Compliance

The proposed rule anticipates separate compliance dates for the revised accounting of disclosures requirements and the new right to receive an access report.

- **Revised accounting of disclosures requirements.** The compliance date will be 240 days after the date that the final rule with the revised requirements is published.
- **New right to receive access report.** The compliance date is dependent upon the date that the covered entity obtained the particular electronic designated record set system. For any system acquired on or before

January 1, 2009, covered entities must produce access reports upon request beginning January 1, 2014. For any system acquired after January 1, 2009, covered entities must produce access reports upon request beginning January 1, 2013. Importantly, HHS believes that it is reasonable to require covered entities to produce, beginning on the applicable compliance date, access reports *that cover the prior three years*. However, HHS specifically requests comments on whether covered entities will be able to generate reports with such historical data.

HHS recognizes that the differing applicable dates established for compliance with the requirement to produce the access report may mean that during 2013 a covered entity would be required to produce a report that includes information about access to some of its electronic designated record set systems (i.e., those acquired after January 1, 2009) but not others (i.e., those acquired on or before January 1, 2009). Consequently, HHS makes clear that covered entities are *encouraged* in this situation to produce access reports that nevertheless include *all* designated record set systems, even if the covered entity is not specifically required to do so.

NEXT STEPS

The AHA plans to submit comments on the proposed rule. We are concerned that the proposed changes will certainly continue – and likely increase – the heavy administrative burdens involved in producing individualized, patient-friendly accounting of disclosures and the newly required reports on electronic access. We have scheduled a conference call to discuss the proposed rule with member hospitals and to obtain feedback to assist us in preparing our specific comments. The call is scheduled for:

Tuesday, June 28, at 3 p.m. ET/2 p.m. CT.

To register for the call, go to <http://www.surveymonkey.com/s/7SQKFBM>.

Also, we urge members to consider submitting comments on the proposed rule that focus on technical capabilities and limitations of the organization's electronic information systems, administrative and resources burdens to the organization of preparing the specific reports requested, and the organization's previous experiences with patient requests and the perceived value to patients of the information requested. Watch for an AHA model comment you can use as you draft and submit your own comments by August 1.

Hospital leaders also should be aware that HHS makes clear in the proposed rule's preamble that the agency intends at a future date to revisit whether covered entities should be required to provide individuals with the right to receive a full accounting for treatment, payment and health care operations disclosures

through an EHR, including a description of the purpose of the disclosure, for all disclosures made through electronic health information exchange (i.e., disclosures that originate from an EHR that are received by another electronic system whether initiated by the disclosing covered entity or provided in response to a query). HHS will determine whether the accounting requirements should be revised to include such disclosures. HHS notes that the agency gave careful consideration to the option as it drafted this proposed rule but concluded that:

[A]ccounting for such disclosures at this time would be overly burdensome when compared to the potential benefit to individuals. Especially for EHR technology that is not certified pursuant to [Office of the National Coordinator] standards and certification criteria, covered entities might need to make substantial and costly modifications to their existing EHR systems in order to track the purpose of disclosures for treatment, payment, and health care operations.

HHS plans to work with the Office of the National Coordinator to assess whether standards for electronic health information exchange should include information about the purpose of each exchange transaction. As HHS notes, “adoption of such standards may significantly reduce the burden on covered entities to account for treatment, payment, and health care operations disclosures through electronic health information exchange.” Hospitals will want to monitor HHS’ progress in this area.

For questions about HHS’ proposed rule, contact Lawrence Hughes, AHA assistant general counsel, at lhughes@aha.org or (202) 626-2346.