Stop? Go? How to Handle Proposed Amendments to the Privacy Rule (HIPAA on the Job)

by Gwen Hughes, RHIA

Privacy rule implementation teams have a dilemma.

The Department of Health and Human Services (HHS) recently proposed amendments to the HIPAA privacy rule aimed at correcting problems related to its implementation. HHS gave the public until April 26 to provide comments. Based on these comments, HHS could finalize some or all of the proposed amendments. The agency could revert to some or all of the existing standards, or it could introduce entirely new standards in areas where amendments were proposed.

Privacy implementation teams are left wondering about their next step: should they wait for publication of a *revised* privacy rule? Execute existing plans to comply with the current privacy rule? Or reevaluate and reprioritize existing plans in light of proposed amendments and move forward?

It's important that organizations position themselves to be in compliance with the privacy rule by April 14, 2003, as required.[1] Therefore, they must reevaluate and reprioritize their privacy rule project plan, tackling implementation of those standards for which proposed changes are minimal or nonexistent, and postponing full implementation of standards that may undergo significant revision. In this article, we'll explore which sections of the rule are ready for implementation and which are best left until later.

Ready to Go

There are many standards in the privacy rule to which no amendments were proposed. Consequently, organizations can move forward in the following areas:

Administrative

- appoint a privacy officer
- appoint a contact person to receive complaints and to provide further information about matters covered in the notice
- define the designated record set
- decide whether they will participate in one or more organized healthcare arrangements

Policies and Procedures

- evaluate and modify the organization's directory content, policies, and procedures
- develop systems for handling patient requests to have communications sent by alternative means or to alternate locations
- decide how patients will be given the opportunity to restrict uses and disclosures of their health information for treatment, payment, and healthcare operations. Determine which restrictions can reasonably be accepted and how granted restrictions will be managed. Develop corresponding procedures
- establish procedures allowing patients access to their health information. Establish procedures for flagging and denying patients access to their health information when necessary
- establish procedures for processing patient amendments, including the acceptance and denial of requested amendments
- evaluate and revise fund-raising policies and procedures as needed. Establish a system for managing patient requests to opt out of fund-raising opportunities

Education and Training

- begin planning content, method, and timing of training for existing members of the work force and those who will join the work force after initial training
- educate patient care providers on HIPAA's standards for communicating with individuals involved in the patient's care (family, friends, etc.)
- decide whether training will be offered to business associates, physicians, or physicians' staff
- explore the operating and capital budget implications of privacy training and request the required resources

Proceed with Caution

There are also standards within the privacy rule where proposed amendments were minimal:

Business Associates

The proposed amendment provides model business associate contract language and gives covered entities (except small health plans who already have until April 14, 2004) an additional year to amend existing contracts. Covered entities are not required to use the model language and can therefore continue efforts to secure revised or amended business associate contracts.

Notice

The proposed amendment would require that direct treatment providers make a good faith effort to obtain an individual's written acknowledgment that he or she received the provider's notice of privacy practices. Organizations can therefore draft the notice describing the organization's information practices, but would be wise to postpone actual printing until the revised privacy rule is published.

Minimum Necessary

The proposed amendment acknowledges that there may be incidental disclosures of protected health information, such as one patient overhearing a fragment of a conversation about another. The proposed amendment makes it clear that incidental disclosures are permissible when they are a by-product of an otherwise permitted disclosure and the covered entity has applied reasonable safeguards. Another proposed amendment to the minimum necessary standard requires covered entities to develop criteria for applying this standard to non-routine requests for health information. Because these amendments clarify HHS' expectations, organizations will be able to move forward with plans to implement the minimum necessary requirements as well.

Disclosures

The proposed amendments attempt to clarify the intent of current standards regarding disclosure to agents of the Food and Drug Administration (FDA), parents, and other providers:

- **FDA-regulated products or activities**: The proposed amendment would ensure that the rule permits covered entities to continue to disclose information to non-government entities subject to FDA jurisdiction about the quality, safety, and effectiveness of FDA-regulated products and activities. For example, the FDA obtains the majority of its information about drugs and devices indirectly from healthcare providers who voluntarily report known adverse events or problems to the manufacturer of the product
- **Parents and minors**: The proposed amendment would clarify that state law governs disclosures to parents
- **Other providers**: The proposed amendment would clarify that covered entities may disclose protected health information, without prior consent, to other covered entities or providers for payment and healthcare operations as well as for treatment. Under the proposed amendment, permitted disclosure would not be limited to other covered entities, but would apply to providers who are not covered entities as well.

As these proposed changes are rather minor insofar as use and disclosure of health information overall, organizations will find that they can evaluate and update policies and procedures related to use and disclosure without too much concern about pending changes to the privacy rule.

Potential Hazards

There are a few areas in the privacy rule in which substantial changes were proposed. Although implementation teams can still move toward implementation in these areas, it may be wise to wait until publication of the revised rule before implementing the final phases of their plans in these areas:

Accounting of Disclosures

The proposed amendment would eliminate the need to track disclosures made pursuant to a valid authorization. Covered entities can still move toward compliance with the standard by identifying any disclosures they'll need to track according to their state law and the current and proposed privacy rule.

If an organization's state laws or regulations, for example, require that disclosures to the individual be tracked, then the organization will need to track such disclosures regardless of the HIPAA standard. Such covered entities will not have to wait to find out if the proposed privacy rule amendment becomes final, because the state law is more stringent and will have to be followed regardless.

Some organizations may decide that it would be best to track disclosures to the individual, even if HIPAA doesn't require it. These organizations may therefore be comfortable moving toward implementation of the accounting of disclosures standard without waiting for the revised rule.

Organizations that prefer to postpone implementation of plans to comply with the accounting of disclosures standard can still consider where requests for accountings will be processed and how information about disclosures will be captured. They may also want to give consideration to any training that will be required. For more information about tracking disclosures, see page 68.

Consent

The proposed consent amendment makes optional the requirement that covered entities obtain a consent for uses and disclosures of information for treatment, payment, and healthcare operations.

While awaiting the revised privacy rule, organizations can discuss whether they want to use a consent if this requirement is made optional. They may also want to discuss where they will capture the acknowledgment that the individual received the notice, if the consent is not used.

Authorizations

The proposed amendment would eliminate the separate categories of authorizations and require that all authorizations contain the following:

- a description of the information to be used or disclosed
- identification of the persons or class of persons authorized to make the use or disclosure
- identification of the persons or class of persons to whom the covered entity is authorized to make the use or disclosure
- a description of each purpose of the use or disclosure
- an expiration date or event
- the individual's signature and date
- if signed by a personal representative, a statement of the representative's authority to act on behalf of the individual
- a statement that the individual may revoke the authorization in writing
- instructions for revoking the authorization or a reference to the notice of privacy practices
- a statement that treatment, payment, or other benefits may not be conditioned on the individual signing the authorization; or when applicable, a statement of the repercussions of refusal to execute the authorization
- in an authorization for marketing, a statement as to any remuneration the covered entity will receive for the marketing information

Because development of the authorization form is not one of the more time-consuming privacy rule requirements, organizations may want to postpone activity relative to authorizations until the revised privacy rule is published.

Marketing

The proposed amendment requires covered entities to obtain the individual's authorization prior to sending the individual marketing materials. Exceptions to the requirement that an authorization be obtained prior to marketing would include communications:

- about a covered entity's services or benefits
- made as part of the treatment of a patient
- for case management or care coordination for that individual
- that direct the individual as to alternative treatments, therapies, healthcare providers, or settings

Exceptions would not apply when the covered entity receives remuneration for marketing from a third party as well.

Organizations may want to discuss how the current privacy rule and proposed amendments will affect their organization's marketing efforts and decide whether there is anything they can comfortably address prior to publication of the revised privacy rule.

Uses and Disclosures for Research

The proposed amendment would modify existing authorization waiver criteria in the current privacy rule with language that more closely adheres to the provisions in the federal policy for the protection of human subjects that governs federally funded research.

The proposed amendment would also eliminate unique requirements for research authorizations and would allow use of the general authorization form described earlier.

Organizations may want to discuss how the current privacy rule and proposed amendments will affect research conducted through their organization and decide whether there is anything they can comfortably address prior to publication of the revised privacy rule.

De-identification

The de-identification requirements in the privacy rule have been a concern to the research community. Researchers believe the requirements are so restrictive that they render disclosed information useless for research purposes. With that in mind, the notice of proposed rule making solicits input on a better method for de-identification.

In addition, the amendment proposes the use of an agreement wherein the recipient agrees:

- to limit use of the data to the purpose for which it was provided
- not to re-identify the information
- not to use it to contact any individual

This is one more area in which organizations may wish to discuss the impact of the current privacy rule as well as the proposed amendment on their processes. They may also be able to identify some tasks that can be performed prior to publication of the revised privacy rule.

Keep Working Toward Compliance

The current privacy rule says that the secretary of HHS may adopt modifications to any standards, but that the compliance date can be no earlier than 180 days after the effective date of the final rule in which the secretary adopts modification. This means that the revised privacy rule will need to be published by mid-October 2002, if covered entities are expected to comply by April 14, 2003.

At this point, it is not known whether the government can review, revise, and publish a new privacy rule by mid-October, and therefore whether HHS will be required to push back the compliance date for some or all of the standards.

Because the likelihood of a compliance date delay is unknown, it is important that covered entities continue to move forward implementing plans to comply by April 14, 2003. As we have seen, there is much covered entities can still do while awaiting publication of the revised privacy rule.

Note

1. Small plans have until April 14, 2004, to be in compliance with the privacy rule.

References

"Standards for the Privacy of Individually Identifiable Health Information; Final Rule." 45 CFR Parts 160 through 164. *Federal Register* 65, no. 250 (December 28, 2000). Available at http://aspe.hhs.gov/admnsimp.

"Standards for the Privacy of Individually Identifiable Health Information; Proposed Rule." 45 CFR Parts 160 through 164. *Federal Register* 67, no. 59 (March 27, 2002). Available at http://aspe.hhs.gov/ admnsimp.

Gwen Hughes *(gwen.hughes@ahima.org) is an HIM practice manager at AHIMA.*

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