Understanding the Privacy Rule's Amendments

by Gwen Hughes, RHIA

By now you know that amendments to the final privacy rule were published in the August 14, 2002, *Federal Register*. The amendments are intended to correct problems identified in the original privacy rule published on December 28, 2000.

This article presents a summary of some of the major changes to the final privacy rule, which will help you and your organization as the countdown to implementation continues.

Notice of Privacy Practices

The amended rule requires that direct treatment providers make a "good faith" effort to obtain an individual's written acknowledgment of receipt of the notice of privacy practices. With one exception for emergency treatment situations, the proposal requires that the good faith effort be made no later than the date of the first service delivery, including service delivered electronically. This notice acknowledgment provision is designed to preserve the initial moment when individuals can discuss privacy practices and concerns with providers in the absence of a consent requirement.

Consent

The amended privacy rule makes optional the requirement that covered entities obtain consent for uses and disclosures of information for treatment, payment, and healthcare operations. Covered entities that obtain consents are also required to obtain written acknowledgements of receipt of the notice. The consent and acknowledgement can, however, be on the same form.

Authorizations

Amendments to the rule allow covered entities to use one authorization form for all purposes. Authorizations must contain:

- 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 for the use or disclosure
- an **expiration date** or event (if an authorization for research does not have an expiration date, this fact must be stated on the authorization form)
- 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 with instructions for revoking the authorization or a reference to the notice of privacy practices
- a statement that treatment, payment, enrollment, or eligibility for benefits may not be **conditioned** on obtaining the authorization if such conditioning is prohibited by the privacy rule, or, if conditioning is permitted, a statement about the consequences of refusing to sign the authorization
- a statement about the potential for the protected health information (PHI) to be **redisclosed** by the recipient
- in an authorization for marketing, a statement as to any **remuneration** the covered entity will receive for the marketing information

Disclosures

Minimum Necessary Standard

The amended privacy rule explicitly permits certain incidental uses and disclosures that occur as a byproduct of use or disclosure otherwise permitted under the privacy rule. Such incidental use or disclosure is permissible only to the extent that the covered entity applies reasonable safeguards and implements the minimum necessary standard when applicable.

The amended rule exempts from the minimum necessary standard any uses or disclosures for which the covered entity has received a valid authorization.

Disclosures for Treatment, Payment, and Healthcare Operations

The amended rule clarifies that covered entities may disclose PHI without consent to other covered entities or providers for treatment, payment, and healthcare operations when the recipient has a relationship with the individual.

Marketing

The amended privacy rule requires that an authorization be obtained for marketing except when marketing communications:

- occur face to face between the covered entity and the individual
- involve a promotional gift of nominal value

Communications that are not considered marketing are those:

- that describe the covered entity's **health-related** products or services
- that are for **treatment** of the individual
- that are for **case management** or **care coordination** for the individual, or directions or recommendations for alternative treatments, therapies, healthcare providers, or settings of care to the individual

Disclosure Fees

The preamble clarifies that it limits only the disclosure-related fees that may be charged to individuals or their personal representatives. The fee limitations do not apply to other permissible disclosures such as those to payers, attorneys, or other entities that have the individual's authorization.

Limited Data Set

The amended rule establishes a new standard and implementation specifications for a limited data set. A limited data set can be used for research, public health, or healthcare operations purposes.

Disclosure of a limited data set requires a data use agreement between the covered entity and the recipient of the limited data set. Such disclosures are subject to the minimum necessary standard but do not require institutional review board approval or a waiver.

The rule specifies that the direct identifiers that must be removed for data to qualify as a limited data set include:

- name
- street address
- telephone and fax numbers
- e-mail address
- social security number
- certificate/license numbers
- vehicle identifiers and serial numbers
- URLs and IP addresses
- full-face photos or other comparable images
- medical record, health plan beneficiary, and account numbers
- device identifiers and serial numbers
- biometric identifiers

The limited data set standard does not require the removal of dates, zip codes, state, county, precinct, or the equivalent information.

Accounting of Disclosures

The amended rule eliminates the need to track disclosures made pursuant to a valid authorization, disclosures that are part of a limited data set, and disclosures that are incidental to another permissible use or disclosure. It allows covered entities to meet the accounting requirement for research (involving at least 50 records) by providing individuals with a list of all protocols for which the patient's PHI may have been disclosed for research pursuant to a waiver of authorization, as well as the researcher's name and contact information.

The amended rule retains the required tracking for public purpose disclosures that do not meet the definition of healthcare operations.

Business Associates

The amended rule includes sample business associate contract language (modified since the proposed rule to clarify ambiguities). The amended rule's transition provisions permit covered entities other than small health plans to continue to operate under certain existing contracts with business associates for up to one year beyond April 14, 2003.

During the transition period, covered entities are not relieved of their responsibilities to make information available to the secretary of the US Department of Health and Human Services, including information held by a business associate. Similarly, the transition period does not relieve a covered entity of its responsibilities with respect to an individual's rights of access, amendment, or an accounting of disclosures by a business associate. Additionally, the covered entity is not relieved of its responsibilities to mitigate harmful effects of an inappropriate use or disclosure of PHI by its business associate.

Privacy is a cornerstone of the HIM profession, so it is important that each HIM professional becomes familiar with the privacy rule. You can view, search, or obtain a copy of the amended privacy rule and future guidance documents from the Office of Civil Rights Web site at www.hhs.gov/ocr/hipaa/.

Reference

"Standards for Privacy of Individually Identifiable Health Information; Final Rule." 45 CFR Parts 160 and 164. *Federal Register* 67, no. 157 (August 14, 2002). Available at www.hhs.gov/ocr/hipaa.

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