LEGAL ISSUES IN COMPLYING WITH HIPAA

How oncology programs can untangle the "Privacy Notice" BY RICHARD B. REILING

he Department of Health and Human Services (HHS) recently issued rules requiring health care providers to provide plain language notices to patients on how protected patient medical information may be used and disclosed. The recently published privacy regulations interpreting the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) rules apply to all "covered entities" that transmit patient data electronically for health care claims or equivalent encounters. Included in this information are:

- health care payment and remittance advice
- coordination of benefits
- health care claim status reports
- health care enrollments and disenrollments
- health plan eligibility information transmissions
- health care premiums
- referral certifications and authorizations
- the first reports of injuries
- health claim attachments.

If providers issue only paper or "hard" copies of this information, the rule does not apply to them. However, most programs transmit the above information electronically.

The regulation (45 C.F.R. 164.520) states that "an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information." Cancer programs offering clinical trials would be well served by understanding this regulation.

How to Comply

To comply, the notice that the provider must write should contain the following elements: 1) a precisely worded header; 2) a description of the types of uses and disclosures for which the health care plan can reveal the information; 3) a separate statement about other special uses; 4) a statement of the patient's individual rights; 5) the ways the health care provider must protect the patient's privacy; 6) how complaints may be filed; 7) the name, title, and telephone number of a person or office in the covered entity that the patient may contact for further information on the privacy issues in the notice; and 8) the effective date of the notice.

Header Each notice must contain the following statement as a header or be prominently displayed somewhere else in the document. "This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully." This statement must be displayed verbatim in bold print. Failure to do so is a violation of 164.520.

Uses and disclosures The notice must contain specific information about how the patient's personal information will be used and must provide:

■ a description (including at least one example) of the types of uses and disclosures of personal health care information the health care entity is permitted to make

a description of each of the other purposes for which the covered entity can use the patient's medical information without the patient's written consent or authorization
 a statement that other uses and disclosures will be made only with the individual's written authorization and that an individual may revoke such authorization.

Special Uses If the health care entity wants to use the patient's protected information for special purposes (i.e., appointment reminders, information about treatment alternatives or other health-related benefits and services of interest to the patient, or fundraising activities), these purposes must be described in the notice.

Statement of individual rights The notice must provide a clear and concise statement of the patient's rights and a brief description on how to exercise these rights. The following rights must be included:

right to request restrictions on certain uses and disclo-

...EACH COVERED ENTITY IS REQUIRED TO SELECT A "PRIVACY OFFICIAL"...

sures of protected health information, including a statement that the covered entity is not required to agree to a requested restriction

- right to receive confidential communications of protected healthy information as provided for by 164.522(b), as applicable
- right to inspect and copy protected health information (as provided by 164.524)
- right to amend protected health information (as provided by 164.526)
- right to receive an accounting of disclosures of protected health information (as provided by 164.528)
- right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.

Covered entity's duties The covered entity must also disclose its own duties.

- It is required by law to maintain the privacy of protected health information and must provide patients with a notice of its legal duties and the privacy practices it is required to follow about protected health information.
- The covered entity must abide by the terms of the notice currently in effect.
- Before a covered entity can change a privacy practice, it must [as prescribed by 164.530(i)(2)(ii)] issue a statement to patients that it reserves the right to change the terms of its notice and put the new privacy practices in effect for all the protected health information it maintains. The statement must also describe how it will issue its revised notice.

Complaints The notice must contain a statement that informs individuals that they may complain to the covered entity and to the Secretary of the Department of Health and Human Services if they believe their privacy rights have been violated. The notice must also contain a brief description of how the individual may file such a complaint with the covered entity and a statement that the covered entity will not retaliate against the individual for filing the complaint.

Contact The notice must contain the name, title, and telephone number of a person or office to contact for further information about privacy rules [required by 164.530(a)(1)(ii)].

Effective date The notice must contain the date on which it first became effective, which may not be earlier than the date on which the notice is published.

o ensure compliance with the cited notice requirements, each covered entity is required to select a "privacy official" to develop and implement the privacy procedures of the entity. A person or office must also be designated that patients can call to obtain information on privacy regulations connected with the privacy notice. The covered entity must train these individuals and its entire staff on privacy issues.

If a covered entity has a web site, the entity's privacy notice must be "prominently posted" on the site and made electronically available from each of the site's sections.

If a patient agrees, in writing, to an electronic notice, the covered entity may send the privacy notice to that patient by e-mail. The patient must agree in writing, since the regulations make it clear that the patient's agreement to receive electronic notice is only good until it is withdrawn. If a patient orally agrees to electronic notification, a good argument could be made that the patient can also orally withdraw the authorization if he or she later desires. Even if the patient has agreed to electronic notification, if the covered entity knows that an e-mail transmission has failed, it must send a paper copy of the notice to the patient. A patient is entitled to a paper copy of the notice from the covered entity on request, even if the patient has agreed to electronic notification of his or her privacy rights.

To provide proof of compliance, a covered entity must keep paper records of the privacy notices it issues. It is a good idea to place a paper copy of such notices in the patient's file.

Summing Up

The HHS Office of Civil Rights will answer questions and provide interpretations of 164.520 to help cancer programs achieve compliance. Still, don't rely solely on assistance from this office since it also conducts compliance reviews and makes referrals for criminal prosecutions. A good source of information and assistance is the American Medical Association web site, http://www.ama-assn.org, which has a special section devoted to HIPAA issues. Also, check the Association of Community Cancer Centers' web site at www.accc-cancer.org for timely updates.

Although complying with 164.520 will increase a practice's expenses, regulatory and civil liability and civil and/or criminal penalties can result if compliance is not achieved. Cancer programs and practices should do everything that is required in the regulations to avoid such penalties.

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