Patient Confidentiality in the 21st Century

Patient confidentiality. These two words have been buzzwords in Congress since 1996, when President Clinton and Congress passed the Health Insurance Portability and Accountability Act (HIPAA) of 1996. The act stipulated that Congress pass national medical-record privacy legislation by August 21, 1999.

After much discussion and debate, Congress was unable to meet this deadline. Therefore, HIPAA requires that the U.S. Department of Health and Human Services (DHHS) issue regulatory standards. In November 1999, the President and DHHS Secretary Donna E. Shalala released a proposal; an extensive communication period ensued, with approximately 55,000 public comments reported.

On December 20, 2000, President Clinton and DHHS released the final rule. Implementation of the final regulation is to come into effect by April 2003 (2004 for entities with revenue under \$5 million). Now, in the 21st century, there are minimum national standards regarding patient confidentiality.

The final regulation includes health plans, health care clearinghouses, and health care providers as covered entities. The provisions apply equally to public- and private-sector health plans and providers. The final regulation applies to all types of personal health information, including oral communication, paper records, and electronic forms. It has the following provisions: consumer control, boundaries on medical record use and release, security of personal health information, accountability for medical records use and release, and protection for psychotherapy notes. These components are included because of careful consideration from the president and DHHS regarding consumers' comments. Below are brief descriptions of the contents of the final regulation. (For a pharmacy analysis, see: www.amcp.org/public/legislative/analysis/032701c.html).

How is a patient's health information

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used? Patients themselves control the use of the information. Providers are required to clearly post notifications of how their information can and cannot be disclosed. Also, a history of disclosures must be made available to patients. Patients must give consent before information is released. Patients have the right to file complaints regarding violations of the provisions of this rule.

Health care providers, including pharmacists, are required under the law to obtain *prior* patient consent before use and disclosure of patient-identifiable information for payment, treatment, and health care operations, including quality assurance and disease-management programs. Providers would be required to post a notification of their privacy policies in clear sight. A health plan would not need to obtain consent for these purposes. However, given the complexities of the rule, it is thought that most health plans would rather be safe than sorry, and obtain consents from enrollees. In order to disclose information for activities other than treatment, payment, and health care operations, the provider or other covered entity would be required to obtain a specific written "authorization," different from the generalized consent, detailing to whom the information would be disclosed and why. These types of activities would include marketing programs and the sale of data.

Under the rule, each covered business entity, including pharmacies, would be required to adopt internal privacy procedures identifying those individuals with access to the information and for what use. The business would be required to hire a privacy officer who must train and moni-

tor employees on the privacy procedures of the organization. In most cases, this requirement would necessitate establishing a new position.

There are strict penalties for violating the privacy rules. While an individual has no private right of action, DHHS can deem that there has been a violation pursuant to a personal grievance filed by an individual, which can trigger criminal penalties for intentional disclosure.

The patient confidentiality rule does not preempt more stringent state laws on use and disclosure of patient-identifiable information. Given this provision, multi-state covered entities will have to ascertain whether federal or state laws govern in the locations where they operate. The answer may well vary from jurisdiction to jurisdiction.

Many organizations, including AMCP, have analyzed the rule and recommended changes to DHHS. Because of many concerns over the impact the final rule will have on the delivery of care, DHHS took the extraordinary step of accepting additional comments on its already published final rule. Many in Congress are already considering whether or not to introduce legislation to fix what they see as flaws in the regulation and the underlying statute. Pharmacists must take active roles in attempting to perfect this regulatory and legislative process to ensure that they can continue to provide optimal care for all patients.

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