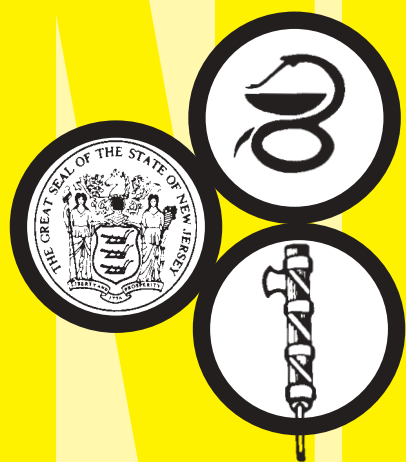


May 2002



New Jersey Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

HIPAA and You

What is HIPAA?

Congress recognized the need for national patient record privacy standards in 1996 when it enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Act included provisions designed to save money for health care businesses by encouraging electronic transactions, but the law also required new safeguards to protect the security and confidentiality of that information. The Act gave Congress three years to pass comprehensive health privacy legislation. When Congress did not enact such legislation, the Act required the Department of Health and Human Services (HHS) to craft such protections by regulation.

How Will HIPAA Impact You?

HIPAA will impact health care providers, health plans, and health care clearinghouses. Health care providers include pharmacies. Specifically, under the administrative simplification component, pharmacies will be affected by four types of rules: privacy, security, transaction and code sets, and identifiers. Pharmacies will be required to use a standardized code set when transmitting claims and will need to adhere to privacy and security standards to safeguard and protect personally identifiable health information (PHI). The fourth type of regulation addresses the use of uniform identifiers for patients, providers, health plans, and employers to help those entities identify and communicate with each other. HIPAA is one of the most comprehensive and complicated federal laws, and its privacy provisions will significantly impact core areas of pharmacy practice.

When Does HIPAA Start?

Privacy Rules

HHS issued final privacy rules that took effect on April 14, 2001. Most covered entities had two full years, until April 14, 2003, to comply with the final privacy rule's provisions. However, on March 28, 2002, HHS proposed changes to the privacy rule. Some of the proposed changes are significant. The proposals would strengthen the privacy notice provisions and remove consent requirements, hindering access to care. Changes were also proposed that would assure appropriate

parental access to their children's records, explicitly require entities (including pharmacies) to first obtain an individual's specific authorization before sending them any marketing materials, and changes to allow the use of a single type of authorization form to obtain a patient's permission for a specific use or disclosure that otherwise would not be permitted under the rule.

Security Rules

The final security regulations have not been published; however, HHS has issued implementation guidance.

Transaction and Code Set Rules

All providers must implement the use of the standardized transaction and code sets by October 16, 2002. The entire pharmacy industry (including software vendors, Pharmacy Benefits Managers [PBMs], and so on) is bracing itself for a change to the National Council for Prescription Drug Program (NCPDP) version 5.1, the HIPAA standard for electronic transactions. Version 5.1 is a variable-length format using new syntax, a number of new data elements, and code values. HIPAA also requires that professional services be billed using the same ASC X12N 837 implementation that physicians will be using. The problem will be that some vendors will be ready to accept NCPDP 5.1 formatted claims sooner than others. However, everyone must be using the new NCPDP 5.1 format by October 16, 2002.

(Congress passed a bill [HR 3323] that amended the HIPAA legislation to extend the compliance date for transaction and code sets until October 16, 2003. However, this extension is available exclusively to those who comply with the conditions outlined in the amended legislation.)

Enforcement

The HHS Office for Civil Rights (OCR) will enforce the HIPAA rules by investigating complaints, conducting compliance reviews, and assessing penalties. Penalties for violating the rules, which are established by statute, range from \$100 per violation to a maximum of \$25,000 for violating each requirement per year. Considering there are more than 25 specific security requirements, the maximum penalty can exceed \$625,000 per year. Wrongful disclosures of health information can lead to fines up to \$250,000 and/or ten years in prison.

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The New Jersey Board of Pharmacy recognizes that these new regulations are complicated and confusing. This brief article is intended only as an introduction to educate and assist pharmacists in complying with the requirements. Requirements may change once HHS publishes final rules. To learn more about HIPAA, visit the HHS Web site at www.hhs.gov/ocr/hipaa.

Editor's Note: Because the **final** privacy and security rules have not been published, the information provided in this *News-letter* may be superseded once the final rules are published.

Some Helpful Tips and Reminders About Controlled Drug Inventories

When conducting a controlled drug inventory, be sure to list Schedule II drugs separately from Schedule III through V drugs. The inventory must be signed and dated by the pharmacist who completed the inventory. The time of day the inventory was taken (opening or closing inventory) must be noted. Finally, be sure that **all** controlled substances are listed on the inventory. Check to ensure that outdated items, refrigerated items, and bulk compound items are included in the inventory.

Board of Pharmacy Subcommittee News

The **Continuous Quality Improvement (CQI) Committee** held its first meeting on April 3, 2002. The Committee has begun investigating and compiling information to address the concerns of the pharmacy community in the area of quality control.

The **Committee on Internship and Externship** is seeking preceptors representing chain, independent, institutional, and industrial practice to serve on the Committee. The Committee is established to advise and assist the Board on all matters relating to the pharmacy internship/externship program. Interested preceptors should forward information about their practice site and a brief curriculum vitae to Edith Micale, Internship/Externship Committee Chairperson, c/o Debora Whipple, Executive Director, New Jersey Board of Pharmacy.

Web Site Reference List

1. Board of Pharmacy e-mail: consumeraffairs@stmp.lps.state.nj.us
2. Board of Pharmacy Web site: www.state.nj.us/lps/ca/boards.htm, click on "List of Professional and Occupational Boards," then click on "Board of Pharmacy."
From the Board site you can access the pharmacy licensee directory, statutes, regulations, Board meeting dates, consumer alerts, and other topics.
3. New Jersey Department of Health and Senior Services Web site: www.state.nj.us/health (for Title 8 Rules and Regulations for long-term care, hospice, and so on.)
4. Drug Utilization Review Council/Generic Formulary Updates: www.state.nj.us/health/mgmt/drugutil.htm
5. Consumer Affairs' Rule Proposals: www.state.nj.us/lps/proposal/proposal.htm
6. Rule Adoptions: www.state.nj.us/lps/ca/adoption/adopt.htm
7. Drug Enforcement Administration: www.deadiversion.usdoj.gov
From this site you can link to other DEA areas.
8. FDA recalls products and provides consumer alerts: www.fda.gov/
9. FDA Title 21 Food and Drug Regulations (CFR): www.access.gpo.gov/nara/cfr
10. Federal Register: www.fda.gov/oc/health/physlabel.html

Please utilize these sites for reference and clarification of statutes and regulations.

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