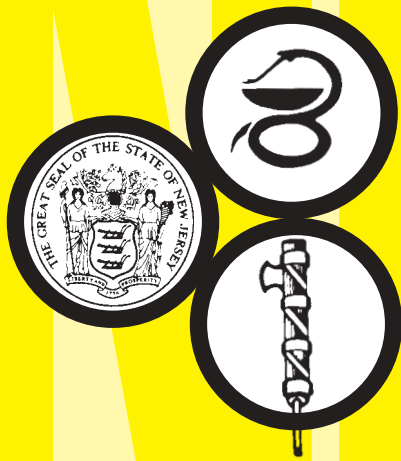


October 2002



# New Jersey Board of Pharmacy

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## HIPAA and You Part II

The Health Insurance Portability and Accountability Act (HIPAA) was discussed in the May 2002 New Jersey Board of Pharmacy *Newsletter* as one of the most comprehensive and complicated federal laws, with privacy provisions significantly impacting the practice of pharmacy. Every pharmacy is required to be "HIPAA compliant" by the implementation deadlines, which are fast approaching. Please reference the May article for a general explanation of HIPAA and the implementation date deadlines.

As expected, the US Department of Health and Human Services (HHS) made some modifications to the privacy requirements when they published their final rules in the *Federal Register* on August 14, 2002.

### Highlights of HIPAA Privacy Rule Changes

The most significant modifications of the privacy rules are:

**Elimination of mandatory consent requirement** – The US Department of Health and Human Services (HHS) eliminated the consent requirement, but imposed a new acknowledgement requirement. Compliance with the acknowledgement requirement will be less burdensome for pharmacies.

**New "Acknowledgement of Notice" requirement** – The new rules require a provider to obtain each patient's "written acknowledgement" that the patient received the provider's notice of privacy policies. If the provider fails to obtain a patient's written acknowledgement, the provider must "document its good faith efforts to obtain such acknowledgement and the reason why the acknowledgement was not obtained." An acknowledgement must be obtained when the notice of privacy policies is distributed. That deadline is extended during emergencies. Only one signed acknowledgement is required per patient. Pharmacies must keep their signed acknowledgements on file for more than six years.

**Note:** In the preamble to the revised rules, HHS writes that "a pharmacist is permitted to have the individual sign or initial an acknowledgement within the log book that patients already sign when they pick up prescriptions, so long as the individual is clearly informed on the log book of what they are acknowledging and the acknowledgement is not also used as a waiver or permission for something else (such as a waiver to consult with the pharmacist)."

**Refill reminders and similar communication defined as treatment, not marketing** – The new rules define "marketing" as "a communication about a product or service. . ." The rules exempt from this definition any communications (1) made for treatment of the recipient, (2) made for case management or care coordination" or to "recommend alternative treatments, therapies, health care providers, or settings of care," or (3) related to health plans, such as describing provider participation in a network or describing prescription drug card programs. HHS "believes that certain health

care communications, such as refill reminders or informing patients about existing or new health care products or services, are appropriate, whether or not the covered entity receives remuneration from third parties to pay for them."

**Signed authorization for marketing required** – The rules now explicitly state that marketing occurs when a third party pays a covered entity for Protected Health Information (PHI), and then the third party uses the PHI to market the third party's products or services. The new rules eliminate the opt-out procedures for health-related marketing. Instead, pharmacies must obtain the patient's prior written authorization before using PHI to make health-related marketing communications that are not made face-to-face, or that do not involve products of nominal value.

**Format and content of authorizations simplified** – When an authorization is required, HHS has streamlined the format for authorization forms. Now only one type of authorization form will be required.

**Certain "incidental" uses and disclosures of patient information allowed** – A new provision inoculates a covered entity (pharmacy) from liability for uses and disclosures that are "incident to" a proper use or disclosure. One example provided by HHS is that no violation occurs if a provider is overheard while sharing PHI with the provider's staff, if the provider "made reasonable efforts to avoid being overheard and reasonably limited the information shared . . ."

**Pharmacies permitted to conduct post-marketing surveillance and make other drug safety disclosures** – Pharmacies can make disclosures to drug manufacturers and others under Food and Drug Administration (FDA) jurisdiction "for the purpose of activities related to the quality, safety, or effectiveness of such FDA-regulated product or activity." This provision only applies to adverse event reporting, recalls, and similar health activities.

**Prescription file buys are allowed** – HHS gave this example: "If a pharmacy, which is a covered entity, buys another pharmacy which is also a covered entity, protected health information can be exchanged between the two entities for purposes of conducting due diligence, and the selling entity may transfer any records containing protected health information to the new owner upon completion of the transaction. The new owner may then immediately use and disclose those records to provide health care services to the individuals, as well as for payment and health care operations purposes."

**Parent and minor relationships clarified** – The rules were revised to further clarify that state law controls the rights of parents regarding a child's PHI.

**Sample business associate contract language and extension** – The rules now give pharmacies an extra year – until April 14, 2004 – to revise existing contracts with business associates. "Sample language" was provided that pharmacies may use in business associate contracts.

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**“Hybrid entity” definition expanded** – Now a drug store may limit the application of the privacy rules to the department that performs the pharmacy functions. The privacy rules need not apply to the front end and other “non-health care components” of the company. Pharmacies that wish to qualify as hybrid entities will have to maintain “adequate separation, in the form of firewalls. . . .”

**Accounting of disclosures streamlined** – Three more types of disclosures are now exempt from the accounting requirements.

**Employer records now exempt** – The rules do not apply to records held by a pharmacy in its capacity as an employer.

To learn more about HIPAA, visit the HHS Web site at [www.hhs.gov](http://www.hhs.gov). From there you can search about Center for Medicare and Medicaid Services, and Office for Civil Rights.

**Editor’s Note:** *The information presented in this update is only intended to highlight general applicable information, and is not intended to be construed as legal advice. You are strongly urged to visit the HHS Web site to learn more information.*

**Note:** *National Association of Chain Drug Stores helped provide information for this HIPAA Update article.*

### **How to Apply for an Extension to the Transaction Standard**

Every pharmacy operation should be ready, along with their software vendor, to transmit pharmacy transaction claims using the National Council for Prescription Drug Programs 5.1 transaction standard by October 16, 2002, or have filed an electronic request with the US Department of Health and Human Services for an extension.

To gain a one-year extension, go to [www.cms.hhs.gov/hippa](http://www.cms.hhs.gov/hippa). Click on “Standard Model Compliance Form” under the heading “HIPAA Administrative Simplification.” Then click on the button that says “Begin the Electronic Submission Process.” Even with an extension, pharmacists should contact their computer vendor to see if their system can support both 3.2 and 5.1 electronic transactions.

### **Medication Errors with Antineoplastic Agents and other High-Risk Medications**

The Board strongly recommends that each pharmacy implement the following steps to minimize the potential of a negative outcome when storing, preparing, and dispensing these agents:

1. Place all antineoplastic agents and other high-risk medications in a separate, designated area of the pharmacy.
2. Always confirm the patient’s diagnosis before filling a prescription for one of these agents.
3. Never fill a prescription for one of these agents that is written using abbreviations. Always call the prescriber to confirm the medication if they have used an abbreviation.

4. Always check the appropriate doses and routes of administration for the specific medication against the dose and route ordered. Confirm the dose as it relates to the patient’s age and size (height, weight, body surface area), as well as the maximum recommended dose for a single dose during both a defined time interval (eg, per day) and a treatment course. Any questions regarding the dose and/or route should be clarified with the prescriber.
5. Always recheck the original prescription when refilling any of these medications.
6. Always verbally counsel the patient or their caregiver when dispensing these agents.

### **Regulatory Guidance**

Questions come before the Board regarding the restocking of drugs, specifically by institutional pharmacies within long-term care facilities or by pharmacies servicing long-term care facilities.

The Department of Health is responsible for licensure of long-term care facilities. Department of Health regulation 8:39-29.4 11(b) 2 requires that, “If a unit dose distribution system is used (“unit dose drug distribution” means a system in which drugs are delivered to the resident areas in single unit packaging), each medication shall be individually wrapped and labeled with the generic or trade (brand) name and strength of the drug, lot number or reference code, expiration date, dose, and manufacturer’s name, and shall be ready for administration to the resident.” The Board of Pharmacy regulation 13:39-9.1 defines long-term care facilities as a “health care facility.” Regulation 13:39-9.3(c) requires written policies and procedures as needed to provide pharmaceutical services to the health care facility. Per 13:39-9.15(a) 2 and 13:39-9.15(a) 3, those written procedures shall comply with the following requirements with respect to unused medications: “If a unit dose packaged medication has been stored in a medication room or secure area in the institution and the medication seal and control number are intact, the medication may be recycled or dispensed.” Any and all medication returned by outpatients of the facility shall not be redispensed.”

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