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New Jersey Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

HIPAA and You – Part IV

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) has been discussed in the past three editions of this *Newsletter*. By the time you receive this *Newsletter*, the compliance deadline of April 14, 2003, for meeting the HIPAA privacy regulation may have already passed.

On February 20, 2003, the United States Department of Health and Human Services (HHS) published the final HIPAA security standards in the *Federal Register*. The compliance date for the security standard will be April 20, 2005. For most pharmacy operations, security rules could surpass privacy in terms of time, money, and resources needed to comply. Pharmacy operators may wish to first contact their software vendor and find out how many of the security requirements the vendor will help implement and how many will have to be done alone or with assistance from a consultant. Just like the privacy regulation, the security regulation also requires significant documentation of policies and procedures. Also like the privacy regulation, the security regulation requires providers to appoint a security official, who may be the same person as your privacy official. In addition to the final security standards, HHS also published some minor changes made to the transaction rule.

Electronic Signature

The New Jersey Board of Pharmacy recognizes that many pharmacy operators are exploring electronic signature capture as a means of obtaining a written acknowledgment that their notice of privacy policy has been received as well as a more private and secure means to record acceptance of prescriptions. Be advised that there are no Board regulations that prohibit electronic signatures for patients.

Time to Renew Your License

The current biennial license period ends April 30, 2003. Here is a review of the applicable laws and regulations governing the pharmacist biennial license renewal.

(A) CE Credits

Each applicant for biennial licensee renewal is required to complete a minimum of thirty (30) credits of continuing education (CE) during the preceding biennial period. Completion of CE credits for an initial renewal of registration are not required.

(B) Think Twice Before Letting Your License Expire

N.J.S.A.45:1-7.1 (b), (c), and (d) provide that any professional license not renewed within 30 days of its expiration

date shall be suspended without a hearing. Any individual who continues to practice with an expired license after 30 days following its expiration date shall be deemed to be engaged in unlicensed practice. A professional license suspended pursuant to this section may be reinstated within five years following its date of expiration upon submission of a renewal application and payment of an additional reinstatement fee.

Very important – Public Law 1999, which prescribes the requirements for reinstatement of professional licenses in New Jersey, changed. At the February 5, 2003 New Jersey Board of Pharmacy Open Session meeting, the Board moved to apply this change prospectively from the January 18, 2000 effective date forward for its licensees. Now an applicant seeking reinstatement of a license more than five years past its expiration date must successfully complete the examination required for initial licensure (North American Pharmacist Licensure Examination™) and submit a renewal application and payment of an additional reinstatement fee.

(C) What is Required for Reinstatement of License

The Board may reinstate the professional license of an applicant whose license has been suspended pursuant to N.J.S.A.45:1-7.1, provided that the applicant otherwise qualifies for licensure and submits the following upon application for reinstatement:

- Payment of all past delinquent renewal fees;
- Payment of a reinstatement fee;
- An affidavit of employment listing each job held during the period of suspended license, registration, or certification, which includes the names, addresses, and telephone numbers of each employer; and
- If applicable, satisfactory proof that the applicant has maintained proficiency by completing the CE hours or credits required for the renewal of an active license.

(D) Inactive Status

A renewal applicant electing to renew as inactive shall not engage in professional or occupational practice within the state. An applicant who selects the inactive renewal option shall remain on inactive status for the entire renewal period unless, upon application to the Board, the Board permits the inactive applicant to return to active status provided such applicant presents satisfactory proof that he or she has maintained proficiency by completing the CE credits required for the renewal of an active license.

Some Practical Advice

Insurance fraud has major consequences including jail time. Be careful – things that you might think are simple might be more complicated than you anticipated.

Do not bill a third party for a full prescription if you only dispense a partial amount. Recently, pharmacies paid millions of dollars in fines for doing this. Do not cut quantities at your discretion.

Class II Prescription Facts

- (1) There are only four items on a Class II prescription that cannot be changed:
 - a. The patient's name
 - b. The date
 - c. The name of the drug (strength can be changed)
 - d. The prescriber's signature

Before you change anything, call the prescriber's office for authorization and document on the script what the change is, who you talked to, the date and time, and your signature.

- (2) Cover prescriptions for call-in Class II emergency prescriptions must be postmarked and mailed to you within three days. It is your responsibility to follow up if you do not get the cover. If the prescriber does not respond in an expeditious manner, you should report the prescriber to the proper authorities.
- (3) Class II prescriptions can be filled up to 30 days after the date written (not three days).
- (4) The quantity on a Class II prescription must also be written in words, ie, #30 (thirty).
- (5) Maximum quantity for Class II is a 30-day supply or #120, whichever is less. The exception to this quantity limitation is for patients suffering pain from cancer, intractable pain, or terminal illness. (See Board of Medical Examiners regulation 13:35-7.6 for specifics.)

Methadone Abuse

Methadone is increasingly being abused by recreational drug users and is causing an alarming rise in overdoses and deaths. Florida, North Carolina, and Maine have all recently reported sharp increases in methadone-related deaths. The surge in methadone deaths appears linked to several factors including the growing abuse of heroin and OxyContin®. Addicts are turning to methadone when they cannot get the other drugs. In most states, the methadone being abused appears to be the tablet form. Addicts either swallow the tablets or grind them into powder that can be inhaled or turned into liquid and injected. Methadone in

liquid form used in drug clinics is also a source of supply. Many clinics across the country, following federal guidelines designed to make methadone treatment more accessible, have stopped requiring patients to take all their daily doses at the clinic, and instead are allowing them to take home doses of methadone once a week or more.

There are no national figures for methadone deaths or overdoses. However, the federal Drug Abuse Warning Network reported that in 2001, 10,725 people turned up in emergency rooms after having abused methadone. That is nearly double the number of such visits in 1999.

NuvaRing Storage and Labeling Requirements

There has been some confusion among pharmacists regarding the prescription contraceptive product NuvaRing® (etonogestrel/ethinyl estradiol). The product can be shipped to pharmacies **without refrigeration**. Once it is received by the pharmacy, it should be stored under refrigeration (36-46° F). After dispensing, NuvaRing can be stored by the patient **without refrigeration** for up to **four months** (77° F). NuvaRing must be labeled with an expiration date that does not exceed **four months** from the date of dispensing.

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