

January 2002



New Jersey Board of Pharmacy

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www.state.nj.us/lps/ca/boards.htm

Published to promote voluntary compliance of pharmacy and drug law.

Board Recognizes Contributions

The New Jersey State Board of Pharmacy wants to express its gratitude for the help of New Jersey pharmacists during the catastrophe at the Twin Towers on September 11, 2001. A huge cooperative effort between New York and New Jersey pharmacists made a real contribution toward restoring health in both communities. The effort was monumental, and you have our thanks.

Bioterrorism Concerns

Many health care professionals have been receiving inquiries about prescribing and dispensing antibiotics for the treatment of bioterrorism. The New Jersey Department of Health Web site at www.state.nj.us/health contains a letter to all New Jersey physicians and physician assistants that can assist you as you educate and counsel your clients. Please look it up for guidance.

The Department of Health has established a bioterrorism phone line at the Emergency Operations Center at 609/538-6030. After hours assistance can be obtained by dialing 609/392-2020.

Knowing and recognizing disease symptoms is key to early detection and effective treatment.

We have the greatest confidence that the public can continue to rely on your professional training, education, and judgment and that you will provide clear and accurate information to the public as you have in the past.

E-mails Requested

In planning responses to bioterrorism and other public health emergencies, the Board of Pharmacy is assembling a list of e-mail addresses of pharmacists licensed in New Jersey. A reply postcard is enclosed for your convenience (postage is required).

Compounding versus Manufacturing

The Board recently received an inquiry about the use of hyaluronidase injection prepared in a retail pharmacy and whether the preparation of this product constitutes manufacturing, not compounding.

Compounding differs from manufacturing in that compounding involves a specific practitioner-patient-pharmacist relationship, a relatively small quantity of medication prepared, and the conditions of sale (specific prescription orders).

The following is required by any New Jersey licensed pharmacy that compounds and/or is the final dispenser of products such as hyaluronidase. These guidelines are based on existing federal and

state regulations, World Health Organization, and US Pharmacopeia guidelines for preparation, sterilization, and sterility assurance.

1. Any batch preparations of a sterile product must be compliant with N.J.A.C. 13:39-11.9.
2. The expiration date must meet the requirements indicated in N.J.A.C. 13:39-11.12.
3. If non-sterile materials are used in the preparation, each batch prepared must undergo proper sterility and pyrogen testing.
4. Each product is to be dispensed by the compounding pharmacy pursuant to a patient-specific prescription. A record of the prescription should also be kept by the pharmacy that is the final dispenser of the product to the patient. The final dispenser may maintain an on-site emergency supply of the product with retrospective dispensing via a prescription sent to the compounding pharmacy as soon as the product is used.

Inspection Report Review

Here is a summary of regulations that are frequently cited for noncompliance by inspectors from the Bureau of Enforcement. The Board encourages you to review your compliance to these frequently cited violations and take corrective measures as necessary.

1. **Expired medications and/or misbranded medications** (N.J.A.C. 13:39-7.13).

Note: Be advised that medications removed from an original manufacturer container and placed in a prescription vial or bottle for dispensing, and then later that same prescription vial or bottle is returned to the active stock shelf without lot and expiration date information included on the label is considered misbranded.

2. **General requirements for controlled drug substances (CDS) records and inventories** (N.J.A.C. 8:65-5.4, 8:65-5.5) **and required biennial inventory of CDS** (N.J.A.C. 8:65-5.7, 8:65-5.14).

Note: All CDS in the possession of the registrant (including outdated items) must be included. The inventory record must indicate whether the count was taken as of the opening or at the close of business and the date the inventory was taken. C-II inventory must be listed separately from C-III through C-V items.

3. **Up-to-date, comprehensive pharmaceutical reference text(s)** (N.J.A.C. 13:39-7.7).

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Notes: Suitable current reference text(s) encompassing the categories listed below are required.

- a) general practice of pharmacy,
- b) drug interactions,
- c) drug product composition, and
- d) patient counseling.

For those who use *Remington's Pharmaceutical Sciences* as a reference text, only the 19th and 20th editions are considered current.

4. Offer to counsel, and pharmacist availability information if patient is not physically present (N.J.A.C. 13:39-7.14(e)1, and 13:39-7.14(e)4.

Board of Pharmacy statutes and regulations can be viewed and downloaded from the New Jersey Board of Pharmacy Web site at www.state.nj.us/lps/ca/boards.htm.

Dichloralphenazone Now Schedule IV

On August 16, 2001, the Drug Enforcement Administration (DEA) placed dichloralphenazone (Midrin®) in Schedule IV. All pharmacies should have taken inventory of dichlorphenazone containing products after September 17. All prescriptions for dichloralphenazone or products containing dichloralphenazone issued on or before October 15, 2001, if authorized for refill, shall, as of that date, be limited to five refills and shall not be refilled after February 12, 2002.

Commercial containers of dichloralphenazone packaged before February 12, 2002, and not meeting labeling and packaging requirements may be distributed until May 13, 2002.

For more information, visit the DEA's Office of Diversion Control Web site at www.DEAdiversion.usdoj.gov.

Prescriber's Name on Label

Advanced Practice Nurses (APNs) have prescriptive authority. N.J.A.C. 13:39-5.9(a)9 states that the prescriber's name must appear on the prescription label. As such, the APN's name must appear on the prescription label. Not infrequently, the collaborating physician's name appears on the label, which can confuse the patient (not to mention the physician if they are subsequently called for assistance by either the patient or the pharmacist). Often the reason cited for having the collaborative physician's name on the label is related to obtaining insurance reimbursement for the patient. In the rare instances where this may be necessary, be sure that the APN's name also appears on the prescription label as the prescriber. APNs must have a Drug Enforcement Administration number in order to write for controlled dangerous substances. A collaborating doctor's number alone is not sufficient.

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