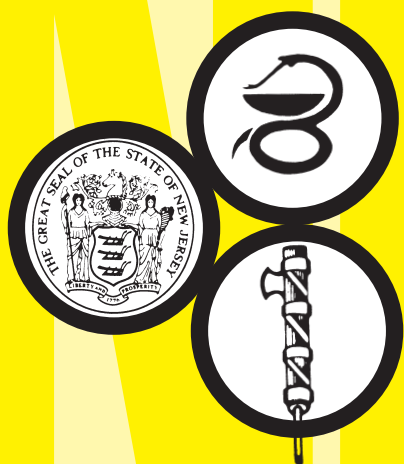


April 2004



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.

New Practice Act Signed!

In January of this year, the New Jersey Legislature passed and Governor James E. McGreevey signed the New Jersey Pharmacy Practice Act. This act, which takes effect in July 2004, replaces the existing pharmacy statute, but it retains several provisions of the current law.

The new statute provides definitions for key terms relative to pharmacists including a comprehensive definition of the practice of pharmacy. Under this act, the practice of pharmacy includes collaborative drug therapy management in accordance with written guidelines or protocols established with a licensed physician and includes modifying, continuing, or discontinuing drug or device therapy; ordering or performing laboratory tests; and ordering clinical tests. This collaborative management shall be conducted in accordance with regulations that are to be jointly written by the New Jersey Board of Pharmacy and the New Jersey State Board of Medical Examiners.

Some of the other changes in the act include:

- ◆ The expansion of the size of the Board of Pharmacy from nine to 11 members.
- ◆ The responsibility of the Board to establish and enforce professional standards and rules of conduct of pharmacists engaged in the practice of pharmacy.
- ◆ The right to seize drugs that constitute an imminent danger to the public.
- ◆ The authority of the Board to register pharmacy technicians.
- ◆ The authorization for a pharmacist to change to a different dosage form than originally prescribed if the prescriber is notified within 48 hours following the dispensing.
- ◆ The ability of pharmacists to administer medications including those given in government-sponsored immunization programs, in accordance with regulations jointly written by the Board of Pharmacy and the State Board of Medical Examiners.
- ◆ The issuance of permits for all practice sites, which includes any site where pharmaceutical care is provided by a licensed pharmacist, not just sites where drugs are dispensed.
- ◆ The registration of out-of-state pharmacies that ship, mail, distribute, or deliver drugs pursuant to a prescription into New Jersey.
- ◆ The provision that a pharmacy technician may accept authorization from a physician for a prescription renewal, provided that the prescription remains unchanged.
- ◆ The ability for a pharmacist to supervise more than two pharmacy technicians if the technicians meet the certification requirements and the pharmacy complies with the defined criteria.

Substitution Guidance

Rule making authority for generic substitution in the State of New Jersey is under the purview of the Department of Health, not

the Board of Pharmacy. The Department of Health recently issued this guidance regarding substitution:

Pursuant to the general supervisory authority, the Commissioner of Health and Senior Services issues the following information:

1. In accordance with N.J.A.C. 8:71, the list of Interchangeable Drug Products (the DURC [Drug Utilization Review Council] Formulary), including all additions and deletions through July 7, 2003, remains in effect until May 17, 2004. All other pertinent sections of the Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1, remain in effect until amended or repealed.
2. The Commissioner of Health and Senior Services is in the process of amending N.J.A.C. 8:71 to allow the Department to use the U.S. FDA Electronic Orange Book as the list of Interchangeable Drug Products in the future.
3. Pharmacists may use the Electronic Orange Book at www.fda.gov/cder/ob to verify approval of new generic products for substitution. When a possible interchangeable product does not appear either on the DURC Formulary or in the Electronic Orange Book, the pharmacist must consult with the prescriber, and obtain permission and confirmation to dispense, see N.J.S.A. 24:6E-8.

Questions regarding substitution should be directed to the Department of Health.

Dispensing Error Alert

GlaxoSmithKline (GSK) recently reported that some patients needing LAMICTAL® (lamotrigine), a medication for treating epilepsy and bipolar I disorder, have mistakenly received other drugs, while other patients prescribed other medications have erroneously received LAMICTAL. The other medications most commonly involved in these dispensing errors are Lamisil®, lamivudine, Ludiomil®, labetalol, and Lomotil®.

Below are helpful recommendations provided by GSK to prevent dispensing errors involving similarly named medications:

- ◆ Place drugs with similar names apart from one another on the shelf.
- ◆ Confirm the brand name prescribed.
- ◆ Remind the patient of the brand name and indication.
- ◆ Provide counseling on how to use the medication properly.
- ◆ Alert patients to carefully check medications they receive and promptly bring any questions or concerns to your attention.

All of these recommendations are sound practices that help to avoid unwanted outcomes in any pharmacy practice site environment.

Regulatory Guidance

Below are frequently cited violations by Division of Consumer Affairs New Jersey Enforcement Bureau inspectors.

- ◆ Accepted and filled prescription for a multi-strength medication with no or incomplete strength.

Pharmacists must contact prescribers when prescriptions for multiple strength combination products such as Percocet® or Endocet® are presented for dispensing without complete indications of strength. Written documentation of the intervention indicating date, time, and contact must be made on the prescription blank. Only the patient, drug name, and prescriber's signature on a prescription written for a CII drug can **not** be altered. Quantity, strength and directions can be altered if contact is made with the prescriber.

- ◆ Not ensuring that the dispensed container's label declares the name of the prescribing practitioner.

Prescriptions issued by authorized prescribers must have the name of the prescriber issuing the prescription on the prescription label. For example, labels indicating the name of the collaborative physician for prescriptions issued by an advanced practice nurse (formerly called nurse practitioner) are in violation of 13:39-5.9(a)9 and 13:39-7.14(b)6.

Required Reference Texts

An up-to-date, comprehensive pharmaceutical reference text and suitable current reference text(s) encompassing the following categories are required to be in every prescription area:

1. The General Practice of Pharmacy;
2. Drug Interactions;
3. Drug Product Composition; and
4. Patient Counseling.

Unabridged computerized versions of these reference texts are acceptable.

Some reference texts may satisfy more than one of the category requirements. The Board maintains a listing, by category, of acceptable reference texts. It is not the Board's intent to exclude reference texts not on the list from being utilized. In fact, the Board encourages licensees to maintain additional reference materials as appropriate to adequately and competently serve patient needs.

For your convenience, here is the current listing of the approved reference texts by category:

1. Comprehensive Pharmaceutical Reference Text (current)

American Hospital Formulary Service Drug Information (Publication Date February 2003)

Clinical Pharmacy Online * Gold Standard Multimedia

Drug Information Handbook – American Pharmacists Association/Charles Lacy 11th Ed 2003/2004 (Publication Date March 2003)

Facts and Comparisons

Lexi-Comp

Micromedex

Thomason

United States Pharmacopeia Dispensing Information (UPS/DI) Volume 1

2. General Practice of Pharmacy (published within the last 10 years)

Martindale The Extra Pharmacopea – 31st, 1996; 32nd, 1999; 33rd, 2002

Remington's Pharmaceutical Sciences * 19th edition, 1995; 20th edition, 2000

3. Drug Interactions (published within the last two years)

Clinical Pharmacy Online * Gold Standard Multimedia

Evaluation of Drug Interactions * First Data Bank

Facts and Comparisons

Facts and Comparisons Interactions

Micromedex

Pharm Index

Remington's Pharmaceutical Sciences

USP/DI Volume I

4. Drug Product Composition (published within the last two years)

American Drug Index

Clinical Pharmacy Online * Gold Standard Multimedia

Facts and Comparisons

Micromedex

Physician's Desk Reference

USP/DI Volume I

5. Patient Counseling (current)

Clinical Pharmacy Online * Gold Standard Multimedia

First Data Bank

Lexi-Comp

Medication Teaching Manual: The Guide to Patient Drug Info

* American Society of Health-System Pharmacists®

Medispan

Micromedex

USP/DI Volume II

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