

New Jersey Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Final Draft of the Joint Proposal on Pharmacist Immunization

The New Jersey Board of Medical Examiners and New Jersey Board of Pharmacy have formulated and approved a final draft which addresses public comments to the proposal previously published in the New Jersey Register. The three major changes in the final draft are as follows:

1. Pharmacists are no longer required to be certified in the use of a defibrillator, or to have a defibrillator on-site when administering immunizations. Therefore, N.J.A.C. 13:39-4.20(b)3 (“Current certification in the use of a heart defibrillator”) has been removed. Accordingly, N.J.A.C. 13:39-4.20(g) (“A defibrillator, which shall be maintained in good working order, shall be available during the administration of vaccines . . .”) has also been removed.
2. The American Heart Association and American Red Cross are no longer the only acceptable providers of current certification in basic life support or resuscitation that would satisfy the requirements of N.J.A.C. 13:39-4.20(b)2. The amended rule now allows pharmacists to be certified in:
 - a. the American Heart Association Basic Life Support (BLS) protocol,
 - b. the Red Cross Cardiac Pulmonary Resuscitation (CPR) protocol for health care providers, or
 - c. a course that complies with guidelines created by the International Liaison Committee on Resuscitation (ILCOR).
3. In order to bring the recordkeeping requirements in line with those of the Board of Medical Examiners, N.J.A.C. 13:39-4.20(l) has been amended as follows: “All documentation and records required to be maintained by this section shall be maintained in either hard copy or electronic form for a period of not less than seven years from the date of most recent entry. . . .” The draft regula-

tion must now undergo internal review in the New Jersey Department of Law and Public Safety. Once approved, the final, adopted rule will be published in the New Jersey Register. The rule will become effective on the day it appears in the New Jersey Register.

Toll-Free Number for Reporting Adverse Events to be Distributed with All Prescriptions

A final rule has been issued by Food and Drug Administration (FDA) (21CFR Parts 201, 208, and 209), which will require all authorized dispensers and pharmacies to provide consumers with a side-effects statement. The statement consists of two parts:

1. a toll-free number for reporting adverse events; and
2. a statement that the number is to be used solely for reporting purposes and not to solicit medical advice.

The effective date for the rule was November 28, 2008, with a compliance date of July 1, 2009. The side-effects statement will be required for all new and refill prescriptions, and may be provided by one or more of the following methods:

1. a sticker attached to the prescription label;
2. a preprinted prescription vial cap;
3. a separate sheet of paper;
4. an addition to the consumer medication information (CMI), and/or;
5. an addition to the FDA-approved Medication Guide.

Disciplinary Actions

The actions listed below include only those where the individual’s license to practice has been revoked, surrendered, suspended, restricted, or reinstated and do not include any other actions taken by the Board. Information regarding the current status of a pharmacist’s license may be obtained either at the Division of

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FDA Web Site Upgrades Support MedWatch's Patient Safety Goal

Two recently launched additions to the Food and Drug Administration's (FDA) Web site are intended to support the "Patient Safety" goal that MedWatch shares in public health efforts to protect patients from serious harm and improve outcomes. The entry pages assist health care professionals and patients to locate timely safety information for FDA-regulated human medical products and assist them in making diagnostic and therapeutic decisions.

The content and links on the new FDA entry page specifically for health care professionals allows busy doctors, pharmacists, nurses, and other health care professionals to find information to make point-of-care decisions. There is information that is specifically safety-related, such as easy access to reporting adverse events or finding new safety alerts, warnings, and recalls. Users can also find content regarding new approvals information, or access to the current version of the label, or prescribing information in "DailyMed." This page can be accessed through www.fda.gov/healthprofessionals.

FDA's other new page is specifically for patients and provides two patient-friendly articles about reporting adverse events and product quality problems to FDA and to the patient's caregivers. These articles are also available to pharmacists in printer-friendly PDF versions that can be downloaded and distributed to patients. FDA relies on properly and timely reporting of serious and unexpected drug and device-related adverse events, use errors, and quality problems. Pharmacists can ascertain and teach their patients to understand the "what, why, and how" to report to FDA and also learn about what happens to each received report and whether it leads to FDA action that may make product use safer for both patients and providers. FDA's patient specific page can be found at www.fda.gov/consumer/default.htm.

Retail Pharmacies Now Providing Medical Clinics to Improve Public Safety




This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with USP and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to **ISMP Medication Safety Alert!**® Community/Ambulatory Edition by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 200 Lakeside Dr;

Horsham, PA 19044. Phone: 215/947-7797. E-mail: isminfo@ismp.org.

Retail pharmacy corporations have set up medical clinics within pharmacies. These nurse-practitioner or physician-assistant run clinics aim to rapidly diagnose and treat a limited number of health problems. Many also offer vaccination programs. The first pharmacy-based medical clinics were opened in Minnesota as QuickMedx in 2000, later becoming MinuteClinic in 2002. Currently there are approximately 1,000 sites in 37 states representing almost three million cumulative visits.

The emergence of pharmacy-based medical clinics offers a unique set of opportunities to improve the safety in prescribing and dispensing medications. Do you have a clinic opening in your store? If so, consider these safety recommendations:

- ◆ Meet the nurse practitioners and physician assistants and introduce them to your staff. Show them how your operation works and invite them in for a tour.
- ◆ If you have prescription scanning capabilities, show them how a scanned prescription displays on your monitor. Show them how different prescription blanks scan (eg, colored prescription blanks, blanks with water marks or seals for diversion) and what to avoid using so as not to distort the actual order.
- ◆ If they are using a device that allows them to send prescriptions electronically, have them send test prescriptions to you, invite them in to see how their prescriptions display on your computer and send them back test refill requests.
- ◆ Work together on any issues that arise, such as conflicting directions and special instructions, where the automatic sig indicates one set of patient directions and then the free text special instructions contradict the sig (see image below).

	LORAZEPAM 0.5MG TABLET
Sig:	1 Tablet(s) PO Q6-8H PRN anxiety, insomnia x 30 days
Dispense:	90 Tablet(s)
Special Instructions:	Take one tab as needed for anxiety or insomnia, may repeat x1.
Refills:	5
Signature:	_____

- ◆ Ask prescribers to include the indication for use whenever they write or call in a prescription.
- ◆ Educate them that it is your policy to read back the entire prescription order to them after transcribing it in the pharmacy including spelling the medication name. Let them know you will be using "cock-pit" language, for example, "one six" for "16."
- ◆ Ask them to include both the generic and brand names on all written orders for medications with look-alike and/or sound-alike names.
- ◆ Share with them ISMP safety tools (eg, List of Error Prone Abbreviations, List of Confused Drug Names) found at www.ismp.org/Tools.



- ◆ Let them know you will dispense measuring devices every time they order a liquid medication.
- ◆ Let them know that safety is your priority when filling prescriptions, and invite them to be part of your safety team.

FDA Launches Web Sites on Promotion of Medical Products

On September 3, 2008, FDA launched two new Web sites to provide information for consumers and industry about how FDA regulates the promotion of medical products. Pharmacists can obtain useful information regarding prescription drug advertising regulations as well as refer their patients who may have questions to the site.

The “Advertising Prescription Drugs and Medical Devices” Web site provides a “one-stop shop” portal to information on FDA regulation of medical product promotion. Pharmacists access relevant laws, regulations, and guidances. This site can be found at www.fda.gov/oc/promotion/.

The direct-to-consumer Web site, “Be Smart about Prescription Drug Advertising: A Guide for Consumers” is designed to educate consumers about how to view such advertising to help inform their discussions with health care providers, and consequently to help improve patient’s understanding and medical care. This site was created in collaboration with EthicAd, an independent, nonprofit organization dedicated to helping consumers, health care professionals, and the pharmaceutical and advertising industries with direct-to-consumer advertising for prescription drugs. More information can be found at www.ethicad.org.

The direct-to-consumer site provides interactive example ads for fictitious drugs to illustrate the different requirements for the various types of ads. It also includes a list of questions patients should ask themselves when they see a prescription drug ad. This list can be printed for patients to use while discussing questions with their health care providers. This site can be found at www.fda.gov/cder/ethicad/index.htm.

FPGEE Returns to Computer-based Format

As advancements in secure testing technology forge ahead, the push for more electronically based systems and less use of the traditional paper-and-pencil mechanisms continues. With this in mind, NABP will soon be returning the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) to a computer-based format, eliminating the paper-and-pencil examination.

The FPGEE is the third computerized examination to be developed by NABP, after the North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®). The new computerized FPGEE will debut at the April 14, 2009 administration.

The computerized FPGEE examination will continue to be administered one day in the spring and one day in the fall; however, instead of limiting the available testing locations to three sites, applicants will be able to choose from more than

200 Pearson VUE testing sites located within the continental United States. In addition, it is anticipated that applicants will be able to schedule their test sites electronically 48 to 72 hours after having been accepted to take the FPGEE.

The NABP test vendor, Pearson VUE, will administer the computerized FPGEE as it does with the NAPLEX and the MPJE. Demonstrating a record of solid customer service combined with a secure and consistent test center network, Pearson VUE is committed to providing a reliable and professional testing environment for applicants on behalf of NABP.

The FPGEE is one component of the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certification process. In addition to passing the examination, FPGEC applicants are required to have certain documents submitted from educational and licensure institutions that present their educational backgrounds and licensure and/or registration to practice pharmacy. Applicants must also pass the Test of English as a Foreign Language™ (TOEFL®) and the Test of Spoken English™ (TSE®), or the TOEFL Internet-based Test (iBT). The FPGEC certificate allows foreign graduates to partially fulfill eligibility requirements for licensure in the 50 United States and the District of Columbia where the certification is recognized.

To prepare for the FPGEE, NABP recommends that applicants take the Pre-FPGEE®, the official FPGEE practice examination written and developed by NABP. This practice examination is designed to help familiarize applicants with the FPGEE by exhibiting the types of questions provided on the actual examination as well as providing a score estimate.

Additional information on the FPGEE as well as the Pre-FPGEE is available in the Examination Programs section on the NABP Web site at www.nabp.net.

Updated 2009 Survey of Pharmacy Law Now Available

The NABP 2009 *Survey of Pharmacy Law*, providing a concise research source for key regulatory questions in pharmacy practice for all 50 states, the District of Columbia, and Puerto Rico, is now available.

The *Survey* updates, graciously provided by the state boards of pharmacy, consist of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Also, a new question in Section VII, “Issuance of Initial Pharmacist Licensure,” asks whether or not states require criminal history record checks for initial licensure as a pharmacist.

To order the *Survey*, visit the NABP Web site at www.nabp.net and download an order form; the *Survey* costs \$20.

All final-year pharmacy students receive the CD-ROM free of charge through the generous sponsorship of Purdue Pharma LP.

More information on the *Survey* is available by contacting customer service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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Consumer Affairs Web site or by calling the License Verification Line at 973/273-8090.

Suspensions

Stephen D. Dwamena, RPh – Respondent on or about May 1, 2003 until on or about October 13, 2004, unlawfully took approximately \$74,600 in medication.

Ordered: Respondent's license to practice pharmacy is suspended, for a period of three (3) years, the initial eighteen (18) months of which shall be served as a period of active suspension, the remainder shall be stayed and served as a probation. *(Filed on January 9, 2008)*

Michelle Gialanella, RPh – Respondent allegedly altered and filled prescriptions for herself and her husband. **Ordered:** Respondent's license to practice pharmacy is suspended effective on issuance of this order, for a period of one (1) year, which shall be stayed and served as probation. *(Filed on March 24, 2008)*

William B. Schobert, III, RPh – Respondent knowingly submitted false prescription claims in the name of himself and other family members while working as a pharmacist. This conduct continued over a period of years which resulted in a loss of \$80,000.

Ordered: Respondent's license to practice pharmacy is suspended for a minimum period of two (2) years from the date of respondent's sentencing until October 19, 2009. *(Filed on April 23, 2008)*

Brian Pucci, RPh – Specifically, respondent obtained employment as a pharmacist and purposely did not show a copy of the prior consent order between respondent and the Board to the employer prior to securing employment. **Ordered:** Respondent's license to practice pharmacy is suspended for six (6) months, all of which shall be stayed. Respondent shall pay to

the Board a civil penalty of \$5,000 for violating the terms of the prior order. *(Filed on May 15, 2008)*

Sanjay Patel, RPh – Specifically, respondent on or about May 5, 2001 and May 8, 2001, intentionally and for no legitimate purpose, forcibly touched the sexual and other intimate parts of another person. Also, respondent on or about May 8, 2001 and May 24, 2001 did knowingly and unlawfully sell a controlled dangerous substance (CDS). **Ordered:** Respondent's license to practice pharmacy effective June 1, 2008, is suspended for a minimum of six (6) months, or until license to practice pharmacy in the state of New York is reinstated without restriction, whichever is longer. *(Filed on May 15, 2008)*

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NEW JERSEY BOARD OF PHARMACY

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