

July 2005



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 Board Members

On March 18, 2005, Acting Governor Richard J. Codey made the following direct appointments to the New Jersey Board of Pharmacy: Edward G. McGinley, RPh (reappointment); Elvy T. Paiva, RPh; Margherita R. Lafragola, RPh; Thomas Francis Egan, PharmD; Marc G. Sturgill, PharmD; Simeon "Sy" Larson, PhD (public member); and Jennifer L. Barron (state executive department member). On May 19, 2005, Acting Governor Codey appointed Axel Miranda (public member) to the Board. With these appointments, the Board has increased from nine to eleven members.

Some of the challenges and opportunities facing this Board – some as a result of the new pharmacy practice act – include:

- ◆ Registering technicians and overseeing the new technician training programs and technician-to-pharmacist ratios.
- ◆ Reviewing the Board's standards for responding to medication errors and impaired pharmacists and technicians.
- ◆ Licensing of all pharmacy practice sites in the state and registering out-of-state and centralized prescription handling pharmacies.
- ◆ Developing rules for Internet pharmacies, pharmacist immunizations, and pharmacist-physician collaborative practice programs.
- ◆ Reviewing the impact of United States Pharmacopeia Chapter 797 on sterile compounding and defining and developing non-sterile compounding versus manufacturing standards.

Past Board Members

As a result of the above appointments, the terms of several dedicated, long-standing Board members have ended. We would like to thank Sophie Heymann (public member); Mona Doyle (public member); Edith Tortora Micale, RPh; Anthony Alexander, RPh; and Robert G. Kowalski, RPh (state executive department member) for the hundreds, and in some cases thousands, of hours that they have spent in service as members of this Board. We owe each of them a debt of gratitude for their service and wish them well in all of their future endeavors.

Requirements for Issuing Written Prescriptions for Medications

The New Jersey Board of Medical Examiners requires (N.J.A.C. 13:35-7.1A) that, except under certain specific circumstances, a practitioner shall not issue prescriptions to an individual without first having conducted an examination, which shall be appropriately documented in the patient record. The practitioner is required (N.J.A.C. 13:35-7.2(d)) to include the following information on each written prescription:

1. The prescribing practitioner's full name, address, telephone number, license number, and proper academic degree or identification of professional practice for which licensed;
2. The full name, age, and address of the patient;
3. The date of issuance;
4. The name, strength, and quantity of the drug prescribed;
5. [Numerical as well as written quantity] to indicate the drug quantity authorized if the prescription is for a Schedule II controlled substance; for example: ten (10) Percodan[®]; or five (5) Ritalin[®] 5 mg;
6. The number of refills permitted or time limit for refills, or both;
7. The handwritten original signature of the prescribing practitioner;
8. An explicit indication, by initials placed next to "do not substitute," if it is the prescribing practitioner's intention that a specified brand-name drug be dispensed;
9. The prescribing practitioner's Drug Enforcement Administration (DEA) number, if the drug is a controlled substance; and
10. Adequate instruction for the patient as to frequency; a direction of "PRN" or "if needed" alone may be used if appropriate.

In addition, it is required that each prescription for a controlled substance shall be written on a separate New Jersey Prescription Blank (NJPB) and any NJPB that contains prescriptions for two or more controlled substances shall be invalid. An NJPB that contains a prescription for only one controlled substance and contains . . . prescription(s) other than another controlled substance shall be valid. N.J.A.C. 13:35-7.2h.

Physician Assistants – Prescriptive Authority for Controlled Dangerous Substances

Effective September 17, 2005, a physician assistant treating a patient in an inpatient or outpatient setting may order or prescribe controlled dangerous substances (CDS) subject to the following conditions:

- ◆ To continue or reissue a CDS order or prescription of the supervising physician, or
- ◆ To adjust the dosage of the original CDS order or prescription of the supervising physician provided there is prior consultation with the supervising physician, or
- ◆ To initiate an order or prescription for a CDS provided there is either prior consultation with the supervising physician or it is part of a treatment plan for a patient with a terminal illness as determined by the supervising physician.

All physician assistant prescriptions must also comply with the following:

Continued on page 4



New Board Will Oversee Management of Drug Safety Monitoring

Food and Drug Administration (FDA) has unveiled a program that aims to improve oversight of drug safety monitoring and to bolster openness in agency product review and decision making. Included is the creation of an independent Drug Safety Oversight Board, made up of medical experts from FDA and other government agencies. Also planned are Web postings of emerging drug data and risk information as well as written materials that provide targeted drug safety information to the public. For more information, see www.fda.gov/oc/factsheets/drugsafety.html.

ACPE Changes Provider Criteria Regarding Drug and Device Manufacturers

In early 2005, the Accreditation Council for Pharmacy Education (ACPE) ceased accepting applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education (CE). Effective July 1, 2005, the organization will no longer recognize pharmaceutical and biomedical device manufacturers as accredited providers. In addition, any CE issued by a pharmaceutical or device manufacturer after June 30, 2005, is not valid. These changes were approved by the ACPE Board of Directors at its January 2005 meeting after the organization determined that manufacturers could not meet both ACPE's requirements and the recommended restrictions as stated in a Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of the Inspector General of the United States (OIG).

In 2003, OIG stated that manufacturers could be subjected to liability under federal statutory provisions if they maintain any influence over CE subject matter or presenters, or provide funding for attendees or other incentives with respect to CE attendance. Strict compliance with OIG's guidelines would relegate manufacturers to solely providing educational grants to CE providers in order to be free of liability. Meanwhile, ACPE's Criteria for Quality require that the CE provider control the content speakers or authors of a CE program, putting ACPE's requirements in opposition to OIG's guidelines; hence, ACPE, out of responsibility to health regulatory boards, the profession, and the public, must now accredit only those providers who are in compliance with the ACPE criteria and the OIG guidelines.

In accordance with ACPE's new policies, organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations and non-health care-related companies, will not be eligible for ACPE accreditation status.

For more information, contact ACPE Executive Director Peter Vlasses at 312/664-3575, or via e-mail at pvlasses@acpe-accredit.org.



Let's Get to the 'Point': Prescription Misinterpretations Due to Decimal Points

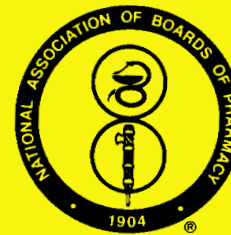
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. 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: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Problem: Numbers containing decimal points are a major source of error and, when misplaced, can lead to misinterpretation of prescriptions. Decimal points can be easily overlooked, especially on prescriptions that have been faxed, prepared on lined order sheets, or written or typed on carbon and no-carbon-required (NCR) forms (often used in hospitals and long-term care facilities). If a decimal point is missed, an overdose may occur. The importance of proper decimal point placement and prominence cannot be overstated.

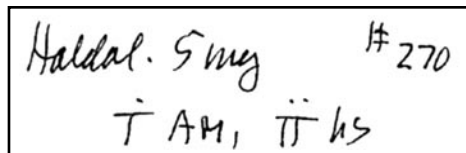
For one, a decimal point should always be preceded by a whole number and never be left "naked." Decimal expressions of numbers less than one should always be preceded by a zero (0) to enhance the visibility of the decimal. For example, without a leading zero, a prescription for "Haldol® .5 mg" (see image shown on next page) was misinterpreted and dispensed as "Haldol 5 mg." We have received similar reports with Risperdal® (risperidone) in which "Risperdal .5 mg" was prescribed (instead of Risperdal 0.5 mg), but the patient received several 5 mg doses because the decimal point was overlooked.

In addition, a whole number should never be followed with a decimal point and a zero. These "trailing zeros" (eg, "3.0") are a frequent cause of 10-fold overdoses and should never be used. For example, when prescriptions have been written for "Coumadin® 1.0 mg," patients have received 10 mg in error. Similarly, a prescription for "Synthroid® 25.0 mcg" could be misread as "Synthroid 250 mcg."

Dangerous use of decimals can also be problematic if they appear in electronic order entry systems or on computer-generated labels. A newly admitted hospital patient told her physician that she took Phenobarbital® 400 mg PO three times daily. Subsequently, the physician wrote an order for



the drug in the dose relayed by the patient. A nurse saw the prescription vial and verified that this was the correct dose. However, prior to dispensing, a hospital pharmacist investigated the unusually high dose. When he checked the prescription vial, he found that it was labeled as “phenobarbital 32.400MG tablet.” The label indicated that 30 tablets were dispensed with instructions to take one tablet three times daily.



The hospital pharmacist contacted the outpatient pharmacy and suggested that the computer expressions including trailing zeros be changed to avoid serious medication errors. The pharmacy management agreed that trailing zeros appearing on labels might pose a risk and made the change immediately.

Safe Practice Recommendations

In order to avoid misinterpretations due to decimal point placement, pharmacists should consider the following:

- ◆ Always include a leading zero for dosage strengths or concentrations less than one.
- ◆ Never follow a whole number with a decimal point and a zero (trailing zero).
- ◆ Educate staff about the dangers involved with expressing doses using trailing zeros and naked decimal points.
- ◆ Eliminate dangerous decimal dose expressions from pharmacy and prescriber electronic order entry screens, computer-generated labels, preprinted prescriptions, etc.
- ◆ Avoid using decimals whenever a satisfactory alternative exists. For example, use 500 mg in place of 0.5 gram, 125 mcg instead of 0.125 mg, or 2 ½ mg instead of 2.5 mg.
- ◆ Identify drugs with known 10-fold differences in dosage strength (eg, Cytomel® 5 mcg and 50 mcg, Coumadin 1 mg and 10 mg, levothyroxine 25 mcg and 250 mcg) and place reminders in electronic order entry systems and on pharmacy shelves to alert practitioners to double-check the dosage strength.
- ◆ When sending and receiving prescriptions via fax, health care practitioners should keep in mind that decimal points can be easily missed due to “fax noise.” Whenever possible, encourage prescribers to give original prescriptions (with an indication that it has been faxed) to their patients to take to the pharmacy for verification. Pharmacists should carefully review faxed prescriptions and clarify prescriptions that contain fax noise.
- ◆ Eliminate the lines on the back copy of NCR forms so that a person receiving can clearly see decimal points or other marks that were made on the top copy.
- ◆ Notify prescribers of the potential for error if misinterpretations due to decimal point usage are discovered.

DEA Issues Final Rules for Electronic Orders for Controlled Substances

On April 1, 2005, Drug Enforcement Administration (DEA) issued final rules regarding electronic orders for controlled substances. DEA revised its regulations to provide an electronic equivalent to the DEA official order form (Form 222), which is legally required for all distributions involving Schedule I and II controlled substances. The regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or purchase Schedule I or II controlled substances. The effective date of the final rules was May 31, 2005.

The final rules were issued via the *Federal Register* on April 1, 2005, and may be downloaded from the following Web site address: www.access.gpo.gov/su_docs/fedreg/a050401c.html.

FDA Publishes Final Rule on Chlorofluorocarbons in Metered Dose Inhalers

FDA announced that albuterol metered-dose inhalers (MDI) using chlorofluorocarbon propellants must no longer be produced, marketed, or sold in the US after December 31, 2008.

The Health and Human Services (HHS) is encouraged that the manufacturers of three environmentally friendly albuterol inhalers are implementing programs to help assure access to these albuterol MDI for patients for whom price could be a significant barrier to access to this important medicine. These programs include MDI giveaways, coupons for reducing the price paid, and patient assistance programs based on financial need.

In a final rule, published March 31, 2005, in the *Federal Register*, HHS stated that sufficient supplies of two approved, environmentally friendly albuterol inhalers will exist by December 31, 2008, to allow the phasing out of similar, less environmentally friendly versions.

FDA Develops PSAs to Educate Consumers About Purchasing Medications Online

FDA recently released two public service announcement (PSA) brochures, which educate consumers about the advantages and disadvantages of purchasing medication online. The brochures also advise consumers to ensure a Web site is a US-licensed pharmacy by contacting their state board of pharmacy. Consumers may want to refer to the list of Verified Internet Pharmacy Practice Sites™ (VIPPS®) on www.nabp.net to find out if a Web site has been checked to make sure it has met state and federal rules. Consumers also will know if an online pharmacy is VIPPS-accredited when they notice the VIPPS Seal on that particular Web site.

For more information on these PSAs visit www.fda.gov/cder/consumerinfo/Buy_meds_online_all_resources.htm.

Continued from page 1

- ◆ The prescription must state whether or not it is written pursuant to protocol or specific physician direction, and
 - ◆ The DEA and license numbers of both the supervising physician and the physician assistant must be on the order or prescription.
- The applicable statute regarding these changes is N.J.S.A. 45:9-27.19 and may be found on the Board of Medical Examiners Web site at www.state.nj.us/lps/ca/bme/htm. Please remember that the name of the prescriber (not the supervising physician) is the name that is required to be on the label of the dispensed product.

Centralized Prescription Handling

In accordance with N.J.A.C. 13:39-4.18, the Board is now accepting applications from pharmacies that wish to engage in central prescription handling. Contact the Board office at 973/504-6450 if you need an application form.

Regulation Highlights

The following items are issues that are often cited by the inspectors and/or are frequently misunderstood and are paraphrased from the current Board of Pharmacy regulations. Please refer to the citation listed at the end of each item to see the complete regulation.

Identification Tags – All personnel working in the pharmacy shall wear an identification tag, which shall include at least the person’s first name and job title (see N.J.A.C. 13:39-6.3).

Prescription Labels – The label on the dispensed container for any product dispensed in any packaging other than the manufacturer’s original packaging shall include the phrase “use by” followed by one year from the date of dispensing or the expiration date from the manufacturer’s container, whichever is earlier (see N.J.A.C. 13:39-7.12).

Reproduction of License – The initial wall license, the biennial license, and the wallet-sized license issued by the Board may not be reprinted, photographed, photostated, duplicated, or reproduced by any other means either in whole or in part (see N.J.A.C. 13:39-2.15).

Display of License – A registered pharmacist who is employed by more than one licensed pharmacy in the State shall have the wallet-sized license issued by the Board with him/her when working at a location where his/her initial wall license and current biennial license are not on display (see N.J.A.C. 13:39-2.10(c)).

Registered Pharmacist-in-Charge – A registered pharmacist-in-charge shall be a full-time employee, employed for a

minimum of 35 hours per week, and shall be physically present in the pharmacy or pharmacy department for that amount of time necessary to supervise and ensure that adequate staffing is present; accurate records are maintained; policies are in place; security is maintained; professional tasks are performed only by authorized personnel; inventory meets all requirements; the prescription area is orderly and sanitary; and personnel comply with all federal and state statutes, rules, and regulations governing the practice of pharmacy (see N.J.A.C. 13:39-6.2(f)).

Automated Medication Systems – A pharmacy may only use an automated medication system to fill prescriptions or medication orders if the Board has conducted an inspection of the pharmacy and system (see N.J.A.C. 13:39-10).

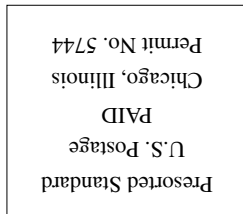
Batch Compounding – The compounding of a quantity of sterile and non-sterile preparations must be supported by a history of prior valid prescriptions or medication orders that have been generated within an established professional prescriber-patient-pharmacist relationship (see N.J.A.C. 13:39-11.8).

Interchangeable Drug Products – Food and Drug Administration (FDA) of the United States Department of Health and Human Services publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book,” is available online at www.fda.gov/cder/ob/default.htm. Drug products with therapeutic equivalence ratings of “A” in this publication are considered interchangeable drug products in New Jersey. In addition, drug products with therapeutic equivalence ratings of “A” that appear on FDA’s “Drugs@FDA” Web site are also considered interchangeable drug products. (Available online at www.accessdata.fda.gov/scripts/cder/drugsatfda) (see N.J.A.C. 8:71-1.1)

Page 4 – July 2005

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