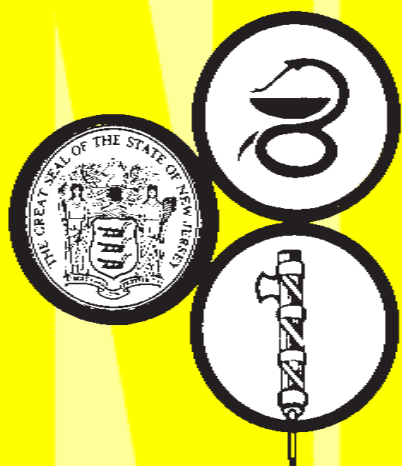


April 2008



New Jersey Board of Pharmacy

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Erratum Regarding the Registration of Pharmacy Technicians

The January New Jersey Board of Pharmacy *Newsletter* erroneously stated that all “certified” pharmacy technicians would be required to register with the Board of Pharmacy. All pharmacy technicians in New Jersey will be required to register with the Board, regardless of certification status.

Please note that pharmacy students working as technicians outside of required school of pharmacy rotations will also be required to register, and will be counted in the pharmacist-to-technician ratio.

In addition, please note that the deadline for registration of New Jersey pharmacy technicians has been extended to December 1, 2008. Although all persons who are currently employed as technicians have until December 1, 2008 to register, technicians should submit their applications as soon as possible to allow time for processing the application, as well as to allow adequate time to complete the required fingerprinting and subsequent criminal history background check. Unregistered pharmacy technicians **may not work** after December 1, 2008, unless they qualify for designation as a pharmacy technician applicant. For more information please view the “Notice of Extension of Deadline for Registration as a Pharmacy Technician,” which was published in the *New Jersey Register* on February 19, 2008, at www.state.nj.us/oag/ca/adoption/pharmnot219.htm. The actual application form is available on the New Jersey Board of Pharmacy Web site.

New Designation for Continuing Pharmacy Education Activity

Beginning January 1, 2009, new designations will be assigned for Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education (CPE) programs. All promotional materials accompanying CPE, including brochures, advertisements, or letters of invitation, should clearly identify

the target audience for the CPE program. CPE programs that target both pharmacists and technicians should include separate learning objectives for each audience. A Universal Program Number will be assigned to each program developed, sponsored, or cosponsored by an ACPE-accredited provider. This number will include the three-digit provider identification number, followed by the cosponsor designation number (see below), the year the program was developed (for example, 09), the sequential number of the program among all programs developed during the year (for example, 001), the format designator (see below), the topic designator (see below), and the target audience designator (see below):

Cosponsor Designators

- 000 – No cosponsor
- 999 – Non-ACPE-accredited cosponsor

Format Designators

- L – Live CPE
- H – Home study
- C – Contains both live and home study

Topic Designators

- 01 – Disease state management/
Drug therapy
- 02 – AIDS therapy
- 03 – Law related to pharmacy practice
- 04 – General pharmacy
- 05 – Patient safety

Target Audience Designator

- P – Pharmacist
- T – Pharmacy technician

As an example, a live CPE program developed by an ACPE-accredited provider (with no cosponsor) dealing with AIDS therapy and intended for pharmacists could have the designation 197-000-09-001-L02-P. If this program was also designed for technicians a second Universal Program Number, in this case 197-000-09-001-LO2-T, would accompany the program.

Continued on page 4



NABP Launches Pharmacy Curriculum Outcomes Assessment Program

NABP launches its Pharmacy Curriculum Outcomes Assessment™ (PCOA®) mechanism in April 2008 for use by schools and colleges of pharmacy in evaluating their curricula. NABP invited schools and colleges of pharmacy to participate in the 2008 administration of the PCOA, scheduled for April 7-18. There will be no fee for participation in this first year of administration.

Those schools and colleges of pharmacy that participate in the April 2008 administration will receive detailed score reports for their students that sit for the assessment, as well as national comparative data. NABP developed the PCOA at the request of schools and colleges of pharmacy and accreditation stakeholders that have expressed a need for a national assessment that is psychometrically validated to assist with measuring curriculum development and student performance.

Details are posted under Assessment Programs on the NABP Web site, www.nabp.net, or by contacting NABP Customer Service at cust-serv@nabp.net.

An e-Educated Consumer is Your Best Customer (Patient)



*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 Food and Drug Administration (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: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

According to the Pew Internet and American Life Project, Online Health Search 2006, 80% of American Internet users, or some 113 million adults, have searched for information on at least one of 17 health topics. Many Americans turn to the Internet before, or instead of, seeking information from their doctor or pharmacist. People want to make better decisions in their lives and therefore seek more in-depth research, research that is offered online.

Patients and caregivers have a vested interest to keep up-to-date on their own or their loved ones' medical conditions. The average doctor's appointment is just 10 minutes – hardly enough time to get into lengthy conversations about treatment options and medication side effects. Long lines, busy and distracted pharmacists, and lack of privacy and confidentiality deter patients from seeking more information from their community pharmacists. It is no wonder then, when patients do not understand medical terminology or want to explore the medication treatment options that are available, they do not call their doctor or pharmacist – they just log on. In the privacy of their home they can find practical information such as lists of foods they should or should not take with certain medical conditions or certain medications. Instead of bothering busy pharmacists

who do not appear to have the time to answer questions, they can get peace of mind when dealing with chronic conditions. They surf the net for reassurance and answers to their questions.

But what about the quality of those online sources? Some are better than others; obviously, Medline offered by the National Institutes of Health is a reliable source, but what if the site is sponsored by a pharmaceutical company? How does the consumer know which information to trust? Research suggests that most health information seekers do not check the source and date of the information they find online. Most Internet users use a search engine and key words from their own limited medical knowledge and rely on the algorithms of the search engines to find them reliable Web sites and scientific articles.

How can you, the pharmacist, help your patients find a credible health care information site? Patients need an easy-to-use, comprehensive medical Web site where they can learn about health conditions and medications. Patients should look for Web sites that offer unbiased health information written by medical professionals.

Tell patients to always check sources and dates of the information provided. For example, information on hormone replacement therapy has changed significantly in the last few years. Articles offering advice and recommendations on drug therapy from 10 years ago could be detrimental to the reader.

The patient-doctor-pharmacist triad has changed. We now live in an era of the square – the patient, doctor, pharmacist, and Internet. Help patients understand what they are reading. Go to the sites yourself and confirm the information is reliable and timely. And of course, find time to answer their questions. Look for a soon to be released consumer Web site being developed by ISMP.

FDA Warns against Using OTC Cold Medicines in Babies

FDA issued a public health advisory on January 17, 2008, recommending that over-the-counter (OTC) cough and cold medicines should not be used to treat infants and children younger than 2 years of age, citing the risk of "serious and potentially life-threatening side effects." FDA held a public advisory committee meeting October 18-19, 2007, to discuss the issue, after which many pharmaceutical manufacturers voluntarily withdrew cough and cold medicines marketed for use in this age group.

FDA says the agency is in the process of evaluating the safety of OTC cough and cold medicines in children 2-11 years of age and will announce its recommendations "in the near future."

The public health advisory is available on the FDA Web site at www.fda.gov/cder/drug/advisory/cough_cold_2008.htm.

Bayer Diabetes Care Recalls Contour Test Strips

Bayer Diabetes Care recently recalled test strips (sensors) for use with the Contour TS Blood Glucose Meter. The company recalled the product because test strips from specific lots could result in blood glucose readings with a positive bias that could demonstrate 5% to 17% higher test results.

This issue is unrelated to the Contour TS meter itself and pertains only to certain test strips used with the meter. Strips used with other Bayer meters are unaffected.

Health care professionals are advised to check the lot number of the Contour test strips in their inventory and contact Bayer Diabetes Care for information on the return and replacement of strips.

More information is available in the manufacturer's press release at www.fda.gov/medwatch/safety/2007/contourTS_recall.htm.



FDA Takes Action against Compounded BHRT Drugs

FDA sent letters warning seven pharmacy operations that the claims they make about the safety and effectiveness of their so-called bio-identical hormone replacement therapy, or BHRT, products are unsupported by medical evidence, and are considered false and misleading by the agency. FDA has expressed concern that unfounded claims like these mislead women and health care professionals.

The pharmacy operations receiving warning letters use the terms "bio-identical hormone replacement therapy" and "BHRT" to imply that their drugs are natural or identical to the hormones made by the body. FDA regards this use of "bio-identical" as a marketing term implying a benefit for the drug, for which there is no medical or scientific basis.

The FDA news release is available at www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html.

Manufacturers to Restrict Distribution of Methadone

As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution of this formulation to only those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals. Manufacturers will discontinue supplying this formulation to any facility not meeting these criteria.

The 5 mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies. The 40 mg methadone formulation is indicated for the treatment of opioid addiction; it is not FDA-approved for use in the management of pain. This measure comes in response to the reported increase in methadone-related adverse events.

For more information, see "Studies Show Increased Methadone-Associated Mortality Related to Pain Management" in the January issue of the *NABP Newsletter*, available on the NABP Web site at www.nabp.net.

New Compounding Standards Effective June 1; USP Offers Webinars

New standards for sterile compounding will become effective on June 1, 2008. United States Pharmacopeia (USP) published the revised General Chapter 797, "Pharmaceutical Compounding – Sterile Preparations" on its Web site in December 2007 to give the compounding community time to implement changes before the effective date.

These revisions tighten standards and conditions for sterile compounding over the previous version of Chapter 797 to help improve patient safety. (See "Sterile Compounding 'Checklist' Revised to Better Protect Patient Health" in the February 2008 issue of the *NABP Newsletter*.) The revisions are included in USP 32–NF 27 and in the second edition of the *Pharmacists' Pharmacopeia*, published in March 2008.

USP is offering a series of educational Webinars and workshops to help compounding professionals appropriately interpret and implement the newly revised standard. The Webinars will provide direct dialogue with two compounding experts and ample time to address questions related to the standard. The workshops will provide added interaction plus hands-on demonstrations related to environmental monitoring, contamination control, and aseptic testing.

Full details on these programs are available on the USP Web site at www.usp.org/hottopics/generalChapter797.html?hlc.

Moving? Need to Transfer Your License?

It is easy – go to the Licensure Programs section of www.nabp.net.

Questions? Call Customer Service at 847/391-4406.

NABP – Serving Pharmacists with Licensure Transfer Since 1904

CMS Names MSAs, Products for Round Two of DMEPOS Bidding

Centers for Medicare and Medicaid Services (CMS) recently announced the metropolitan statistical areas (MSAs) and product categories for the second round of the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program.

All suppliers must meet quality standards and be accredited by a CMS-recognized accreditation organization, such as NABP, to obtain a contract under the Medicare DMEPOS competitive bidding program. The final deadline for all suppliers to obtain accreditation is September 30, 2009. However, CMS encourages suppliers to seek accreditation as soon as possible to avoid any potential difficulties that would affect their ability to bid.

The competitive bidding program is designed to improve the effectiveness of Medicare's DMEPOS payments, reduce beneficiary out-of-pocket costs, and save the Medicare program money while ensuring beneficiary access to quality DMEPOS items and services. More information, including the lists of MSAs and product categories, is available on the CMS Web site at www.cms.hhs.gov/CompetitiveAcqforDMEPOS.

Adverse Event Reporting Requirements in Effect for OTC Products

FDA recently issued new adverse event reporting requirements for manufacturers, packers, and distributors of dietary supplements and over-the-counter (OTC) drug products marketed without an approved application. The new reporting requirements, as described in Public Law 109-462, became effective on December 22, 2007.

The act, as well as the FDA *Guidance for Industry: Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed without an Approved Application*, is available via the FDA MedWatch site at www.fda.gov/medwatch/otc.htm.

FDA Rule Calls for Toll-Free Number for Adverse Events on Drug Labels

FDA recently issued an interim final rule requiring certain medication labels to include a toll-free number for reporting adverse events. The interim final rule codifies provisions of the proposed rule "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products" that became effective on January 1, 2008, under the FDA Amendments Act of 2007. The rule does not apply to over-the-counter medications approved as new drugs if the product packaging includes a manufacturer's or distributor's toll-free number for reporting complaints.

To allow manufacturers, dispensers, and pharmacies time to update their labeling and systems to comply with the new requirements, FDA will delay enforcement actions regarding these regulations until January 1, 2009.

More information is available in the *Federal Register* (Docket No. 2003N-0342) at www.fda.gov/OHRMS/DOCKETS/98fr/E7-25426.pdf.

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As pharmacists, please make certain any CPE program you complete is denoted with the correct target audience designator.

Proposed Immunization Rule Published for Public Comment

The proposed rule "Procedures for Physician Ordered or Government Sponsored Immunizations Performed by Pharmacists" was published in the *New Jersey Register* on March 3, 2008, for public comment. The public has 60 days to submit comments. A form is provided for submitting comment on the Web site at the following address: www.state.nj.us/oag/ca/proposal/bmepro33.htm.

New Jersey Senate Bill 1604

New Jersey Senate Bill 1604, signed by Governor Jon Corzine on January 4, 2008, amends the New Jersey Controlled Dangerous Substances Act to allow the use of electronic order forms (commonly known as 222 forms) in New Jersey. Section 14 of P.L.1970, c.226 (C.24:21-14) is entitled "Order Forms." As amended, C.24:21-14(d) reads: "Use of an official written order in electronic form shall comply with the requirements of State law and regulations." The use of electronic ordering took effect immediately.

This bill also establishes new requirements for New Jersey Prescription Blanks. As amended, Section 20 of P.L.2003, c.280 (C.45:14-59) reads in part:

The Division of Consumer Affairs in the Department of Law and Public Safety shall establish the format for uniform, non-reproducible, non-erasable safety paper prescription blanks, to be known as New Jersey Prescription Blanks, which format shall include an identifiable logo or symbol that will appear on all prescription blanks. The prescription blanks for each practitioner or health care facility shall be numbered consecutively and if the prescriber or health care facility has a Na-

tional Provider Identifier, the prescription blank shall include the National Provider Identifier.

The use of the new New Jersey Prescription Blanks with the consecutive numbering and the National Provider Identifier will go into effect on October 1, 2008.

In addition to the above changes, this bill moved the responsibility for oversight of controlled substances from the Department of Health and Senior Services to the Division of Consumer Affairs in the Department of Law and Public Safety and established a Prescription Monitoring Program, which will consist of an electronic system for monitoring controlled dangerous substances that are dispensed in or into the state by a pharmacist in an outpatient setting. We will include information regarding the Prescription Monitoring Program in future *Newsletters* as the Division of Consumer Affairs develops this program.

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