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SC Department of Labor, Licensing, & Regulation – Board of Pharmacy

Kingstree Bldg, 110 Centerview Dr
PO Box 11927, Columbia, SC 29211-1927
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Published to promote voluntary compliance of pharmacy and drug law.

Facility Permit Renewals Are Coming!

The permit renewal notices and forms were mailed out the beginning of April 2008 to the last known address we have on file. If you are a permit holder and have not received your permit renewal application, contact the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy office immediately. The renewal notice you receive will contain a user ID and password that will allow you access to the online renewal Web site. The online renewal system has been enhanced for ease of use and your convenience during the renewal process. If you choose not to renew your permit online, you may request a renewal form from the Board or print a renewal form from our Web site at www.llr.state.sc.us/pol/pharmacy. The completed form along with proper fees should be mailed to the Board at PO Box 11927, Columbia, SC 29211. The permit renewal applications have been modified to require your Federal Employer Identification Number for proper tracking of South Carolina facilities.

All applications must be received at the Board's office prior to June 1, 2008, or a \$50 late fee will be assessed. After June 30, 2008, the facility permit will lapse. Upon application for reinstatement, the facility will be assessed a penalty of \$10 a day until the permit is reinstated, plus the \$50 late fee and the new application fee. Depending upon the circumstances, the facility, the pharmacist-in-charge, and/or the pharmacists who practice in the pharmacy may be charged with violations of the practice act for operating without a permit pursuant to Section 40-43-83. Sanctions can include civil penalties, reprimands, or requirements for additional continuing education (CE).

Compliance Tips: Getting Ready for USP 797 and USP 795 Inspections

United States Pharmacopeia (USP) Chapter 797, "Pharmaceutical Compounding – Sterile Preparations" and USP Chapter 795, "Pharmaceutical Compounding – Nonsterile Preparations" current and revised, are being used as the reference standards of practice for new and permitted facilities renewing by June 30, 2008. The time for compliance with the requirements for construction of the negative pressure area for hazardous preparations and nuclear medication preparation areas has been extended until December 31, 2008.

All facilities will need policies and procedures covering all types of products made, cleaning processes, and environmental monitoring and testing. Documentation for cleaning, testing, and monitoring must be specific and contain the time, date, and initials of the person performing these activities. Environmental monitoring should not be done immediately after cleaning, but at the end of a shift or work of the day.

Any deviation from the provided beyond use date (BUD) or expiration shall have documentation of validation or professional formulas to extend the BUD. Be sure that the BUD is on the final product.

Be sure that the professional testing personnel are providing you with reports for each hood, buffer, and ante area with a grid of where air sampling is done. Compounding Aseptic Isolator or Compounding Aseptic Containment Isolator (glove boxes) should be unidirectional and meet Controlled Environmental Testing Association guidelines.

In the revised USP 797 standards, the two new risk categories for compound sterile preparations (CSP) are low-risk level with 12-hour or less BUD and immediate use CSPs. Immediate use is not intended as a loophole for satellite pharmacies, but they are allowed to use the low-risk 12-hour BUD. This category still requires the gloving, gowning, environmental monitoring and testing, and the floor should be mopped in the segregated area daily.

There have been many questions concerning humidity monitoring ranges for USP 797 and USP 795. The range is 35% to 60% with a typical tolerance range of 2% to 10%. At a previous program by a microbiology consultant, it was noted that below 35% there can be static electricity and above 60% there is an increase in growth of bacteria.

As a clarification for USP 795, there have been questions concerning which products fall under each category. Examples of non-aqueous liquids and solid formulations would be fixed oil solutions and suspensions, capsules, suppositories, and effervescent. For water-containing formulations examples are aqueous solutions or suspensions, gelatin and troches. For all other formulations examples include creams and gels.



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.

Educational Requirements/Training for Personnel Compounding

At the January 16, 2008 Board of Pharmacy meeting, the Board voted to further define the CE for USP 797 and USP 795 to require entities or facilities involved in compounding (sterile and/or nonsterile) to have an educational component for all personnel involved in the compounding process. Evidence of employee training must be documented in the employee file at the pharmacy. Each employee must have six hours of initial training documented and must have four hours of CE or training on an annual basis. This education does not have to be Accreditation Council for Pharmacy Education or Continuing Medical Education – Category 1, **unless** you are planning to use the CE for renewal of your pharmacist license or pharmacy technician registration.

In addition, USP 797 requires evidence of training and/or CE in compounding sterile products with **written test and didactic review annually**. Logs for media-fill and glove-tip testing sufficient for risk level (annually for low and medium; every six months for high) must be kept available for review. When applicable, personnel must be trained in hazardous material handling and precautions with annual documentation.

Repackaging of Legend Drugs

If your pharmacy dispenses medications to patients in nursing homes, long-term health care facilities, assisted living homes, or the Department of Veterans Affairs, please review this article carefully. If a patient in the facility receives medication from another pharmacy and the facility director of nursing or director requests that you repack the medication into unit dose, you **cannot** legally repack any drugs dispensed on prescription by another pharmacy. To legally perform this service, you must register with Food and Drug Administration (FDA) as a repacker and you must have lot numbers and expiration dates of the medication that must be received in the manufacturer's sealed original container. Because some medications are not available in unit dose, you may legally repack medications purchased

by your pharmacy from a wholesaler or distributor into unit dose and dispense these medications to the patient. Proper records must be kept according to the South Carolina Pharmacy Practice Act; however, to perform this function you do not have to register with FDA as a repacker. If you sell unit dose medications repackaged by your pharmacy to another pharmacy, you must be registered with the FDA as a repacker/wholesaler.

Misbranded

According to the South Carolina Code of Laws, § 39-23-40, a drug or device shall be deemed to be misbranded:

- (a) If its label is false or misleading in any particular ... (i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

Upon recent inspections, it has been determined that some facilities are using the incorrect National Drug Code (NDC) or manufacturer and/or not changing the NDC or manufacturer when a different medication is used upon the refill of prescriptions.

A pharmacist is also required to ensure that the generics you are using for substitution of a brand name product are AB rated for the particular brand. Each time a new generic brand is received, it should be checked for the appropriate AB rating. The *Orange Book* is available online free at www.fda.gov/cder/orange.

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Lee Ann F. Bundrick, RPh, Administrator - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Communications Manager

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National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056
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