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News

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

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2014 Pharmacist Renewal Notices Are Coming Soon!

The 2014 renewal notices will be mailed to you in late February. The South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy has enhanced its online renewal system to make it easier and more convenient for you to renew your license. You will receive a renewal notice with a **user ID** and a **password** that will allow you to access the online renewal website. If you choose not to renew online, you can request a paper renewal form from the Board office and renew by mailing the completed form and proper fees to that office. Applications for renewal must be filed before March 31, 2014, to avoid a penalty. If you do not renew online, please document the date the application is mailed. The Board recommends the paper renewal be sent via **certified mail with a return receipt requested.** Postage machines do not provide acceptable proof of mailing.

Applications submitted for renewal between April 1 and April 30, 2014, must include a penalty fee of $50 for late renewal in addition to evidence that the applicant meets the renewal requirements and has paid the appropriate fees. If you do not renew your license by April 30, 2014, it will be considered lapsed. You may be disciplined for unlicensed practice if you continue to work in South Carolina after that date.

Pharmacist Continuing Education Requirements for Renewals

To renew online, you must indicate you have completed the required 15 hours of continuing education (CE). Six of those hours must be live and 50% must be in drug therapy or patient management. **You cannot renew until you have completed the CE requirements.** After renewals are processed, a random CE audit will be conducted. If you are selected for the audit, please respond promptly. Disciplinary action will be taken if you cannot show you completed the CE requirements or if the required CE is dated **after** your renewal was received in the Board office.

South Carolina Reporting & Identification Prescription Tracking System

South Carolina Department of Health and Environmental Control's (DHEC) Bureau of Drug Control appreciates the cooperation of South Carolina dispensers as DHEC has enhanced its reporting standards to include an upgrade to American Society for Automation in Pharmacy 4.2 and daily reporting. This South Carolina Reporting & Identification Prescription Tracking System (SCRIPTS) upgrade and daily reporting will result in up-to-date useful data for our pharmacists and clinicians. If you have any questions concerning reporting requirements, please visit DHEC's website at *www.dhec.sc.gov/scripts.* The website includes frequently asked questions (FAQs), policy statements, and the *Dispenser's Implementation Guide* for your reference.

Update to Changes in Acetaminophen Combination Products

In January 2011, Food and Drug Administration (FDA) announced a request for manufacturers of oral prescription acetaminophen combination products to limit the maximum amount of acetaminophen to 325 mg per tablet, capsule, or dosage unit. Drug manufacturers had until January 14, 2014, to comply with the limitations. **There have been no regulatory or statutory restrictions placed on the continued dispensing of higher strength acetaminophen combination prescription products.** Health care providers are encouraged to review the new warning labels, etc, and provide patient counseling as appropriate.

You may review further FAQs on the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm239821.htm.*

Changes to Fentanyl Pain Patch Warnings Required by FDA

To reduce the risk of accidental exposure, Food and Drug Administration (FDA) has announced new requirements that change the appearance of fentanyl pain patch warnings to make them more visible. The change also requires new language in the warning that emphasizes the risk of death from accidental exposure, particularly in children. The announcement coincided with a Consumer Update that stressed the potential danger of improperly discarded fentanyl patches to children and pets. FDA reminded consumers of the agency's previous advice for securely storing unused patches and disposing of used fentanyl patches by folding the sticky sides together and then flushing them down the toilet. The agency also advises patients to cover in-use patches with an adhesive film to keep them from coming loose, and to regularly check patches to ensure they are securely in place. FDA offers additional information for health care providers on the "Fentanyl Transdermal System (marketed as Duragesic) Information" page, available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm114961.htm*. Consumer information about safe drug disposal methods is also available on the AWAR$_X$E® Web site at *www.AWARERX.ORG*.

New: Free ISMP Medication Safety Alert! Newsletter for LTC Facilities

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes 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 risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In July, ISMP began publishing *Long-Term Care Advise-ERR,* a new *ISMP Medication Safety Alert!* newsletter for nurses and administrators in long-term care (LTC) facilities. ISMP receives error reports that have occurred in LTC facilities. The newsletter is provided free to LTC facilities in the United States thanks in part to corporate sponsorship from Lilly and for a nominal subscription fee for pharmacies that service LTC facilities and others. Please visit ISMP's Web site at *www.ismp.org/Newsletters/longtermcare* for more information, and let your LTC facilities know about this free offer.

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

A physician called a LTC facility to change a resident's oxycodone order from an extended-release formulation to an immediate release formulation at the same dose and frequency. The nurse receiving the verbal order transcribed it as "Discontinue OxyContin 10 mg BID, Start OxyContin 10 mg IR BID," with "IR" meant to represent immediate release. Although Oxy**Contin**® is a brand of oxy**codone,** it is only available as an extended-release tablet. The pharmacy had previously been dispensing Oxy**Contin** for the resident, so the nurse thought she could communicate the prescriber's order by discontinuing the current Oxy**Contin** order and then ordering Oxy**Contin** as an immediate-release product. The pharmacy continued dispensing Oxy**Contin.** The differences between these products and formulations were brought to the attention of nursing staff via an in-service. To minimize the risk of confusion, do not attach modifiers such as "IR" for immediate-release or "RS" for regular strength unless it is part of the official drug name.

Errors Occur During Transitions of Care

A pharmacist reported the following hazardous situation that can occur during a hospital to LTC transfer. Residents are often admitted to a LTC facility with a list of medications printed from the hospital pharmacy computer. On these printouts, doses are expressed along with the number of tablets. For example, the printout may list hydrochlorothiazide 50 mg/2 tablets daily for an order in which the total dose was 50 mg because the hospital only stocks the 25 mg tablets. During hospitalization the patient required two tablets for each dose; however, the LTC nurse may misinterpret the order to mean two 50 mg tablets, making the total dose 100 mg, or two times more than prescribed. This issue arises every time the resident's total dose in the hospital requires more than one tablet or capsule. Discharge medication summaries and transfer orders should only list the total dose in mg or mcg and other directions for use (ie, frequency, route, drug name) to avoid misinterpretation.

2013 USP Chapter <797> Compliance Survey Shows Compliance Trends Unchanged From 2012

The 2013 United States Pharmacopoeia (USP) Chapter <797> Compliance Survey, the third annual report released since 2011, shows that the overall compliance rate of 77.2% remains nearly unchanged from the 2012 rate. Budgetary restrictions and physical plant limitations were among the top challenges to compliance by survey respondents. The report also details the

survey's findings on what types of facilities are participating in compounding, and compliance in specific domain areas such as environmental sampling and gloved fingertip sampling. Of the survey's 1,045 participants, 97% of the survey's respondents said that USP Chapter <797> "has had a positive influence on patient safety." The report notes National Association of Boards of Pharmacy® (NABP®) efforts to assist state boards of pharmacy in evaluating pharmacy compliance with USP Chapter <797> requirements for sterile compounding in their states. The report also noted that those who participated in the 2011 survey had a higher compliance score than those who did not. The survey's authors encouraged pharmacy owners with multiple areas of noncompliance to target one or two areas to improve. They also encouraged organizations that participated in the survey to make use of the free Action Plan – generated upon completion of the survey – and other free resources to "reshape" their sterile compounding practices. The full report on the survey's results is available in the October 2013 issue of *Pharmacy Purchasing & Products Magazine* and on the magazine's Web site at *www.pppmag.com/article/1403*.

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

FDA planned to submit a formal recommendation to reclassify hydrocodone combination products as Schedule II controlled substances to the Department of Health and Human Services by early December 2013. FDA expects the National Institute on Drug Abuse to concur with the recommendation, indicates a statement on the FDA Web site. FDA also indicates that while "the value of and access to these drugs has been a consistent source of public debate," the agency has "been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse." Drug Enforcement Administration makes the final decision about the appropriate scheduling of these drugs. In January 2013, FDA's Drug Safety and Risk Management Advisory Committee made a recommendation that hydrocodone combination products be classified as Schedule II drugs following a 19-to-10 vote that concluded a two-day meeting during which members discussed the potential for abuse and misuse of the medications and the potential impact of rescheduling the drug products. FDA's statement on the recommendation is available at *www.fda.gov/Drugs/DrugSafety/ucm372089.htm*.

New FDA Drug Info Rounds Training Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm* and *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm,* respectively. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

CPPA Developing Specialty Pharmacy Accreditation Program

The Center for Pharmacy Practice Accreditation® (CPPA) has announced the development of a new accreditation program for specialty pharmacy practices. CPPA Executive Director Lynnae Mahaney, MBA, RPh, FASHP, VHA-CM, indicates that "CPPA will be able to develop the new specialty pharmacy standards quickly and efficiently with the existing standards development methodology, infrastructure, and network of specialty pharmacy expertise."

CPPA is a partnership between the American Pharmacists Association, the American Society of Health-System Pharmacists, and NABP. CPPA develops and implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. CPPA offers the general public and users of pharmacy services a means of identifying those pharmacies that satisfy the accreditation criteria and are focused on advancing patient care, safety, and quality.

More information may be found in the press release, available at *www.pharmacypracticeaccredit.org/news/2013/10/cppa-to-develop-specialty-pharmacy-accreditation-program*.

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Board Welcomes New Investigator/ Inspector

Ray Trotter joined the Board staff as a pharmacist investigator/inspector on December 18, 2013. He holds a bachelor of science degree in pharmacy from the University of South Carolina College of Pharmacy. Trotter has been a pharmacist for approximately 40 years and has 35 years of experience in investigative work as a pharmacist. He has an extensive background and work history in pharmacy, diversion, investigations, audits, inspections, and regulatory/law enforcement related to the profession of pharmacy. He has practiced in retail, independent, nuclear, sterile compounding, and consultant settings. Mr Trotter, his wife, Becky, and their children live in Lexington, SC. The Board and staff are happy to welcome him as a full-time employee.

CE Requirements for Pharmacy Technicians and State-Certified Pharmacy Technicians

- Ten hours of Accreditation Council for Pharmacy Education (ACPE) or continuing medical education (CME) Category I CE are required each registration year for renewal. Of the 10 hours, a minimum of four hours must be "live" hours. CE must be taken **before** renewing a registration each year.
- **There are no exemptions to the CE requirement for technicians.**
- Technicians may take CE that is designated for pharmacists (P) or technicians (T); however, the subject matter of the CE should be within the scope of a technician's practice.
- To determine if CE is live (L), home (H), or combination (C), refer to the ACPE universal program number (UPN). Example: Live CE will have an "L" in the UPN, eg, 430-000-092-021-L01.
- All CME Category I hours are live hours.
- Hours completed in excess of the requirements may be carried forward in the next registration year but may not be carried forward for more than one registration year. It is the responsibility of the technician to keep up with excess hours that can be forwarded to the next registration year.

Please note that college health-related fields are not acceptable in lieu of the required CE hours.

Compliance Reminder – The Board Is Looking to Hear from You!

Please update the Board office when your pharmacy has a change in employees such as new hire or resignation. This information is a part of the pharmacy permit renewal application; however, in some instances that is the only time the Board is notified.

According to law, all licensed pharmacists, registered pharmacy technicians, state certified pharmacy technicians, and pharmacy interns are required to notify the Board in writing within 10 days of their change of employment. He or she should give the name and address of the permitted facility at which he or she was last employed and the name and address of the expected future employer. If possible, please submit the pharmacy permit number of each permitted facility.

The *South Carolina Board of Pharmacy News* is published by the South Carolina Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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