Upcoming Board Vacancy

If you live in the Fourth Congressional District and are interested in serving on the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy, you may petition to be a candidate to serve on the Board. You must meet the following requirements:

♦ Reside in the Fourth Congressional District;
♦ Be licensed and actively practicing pharmacy in South Carolina; and
♦ Before December 1, 2013, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the Fourth Congressional District.

The term begins July 1, 2014 and ends June 30, 2020.

After receiving biographies and petitions, the Board administrator will:

♦ prepare and mail ballots by January 15, 2014, to all pharmacists who have notified the Board they reside in the Fourth Congressional District; and
♦ certify as true and valid all ballots postmarked before February 25, 2014, and received by the Board office before February 15, 2014.

Before March 1, 2014, the Board will certify in writing to the governor the names of the three candidates receiving the most votes in the election and the name of the person who the nominee will replace on the Board. The new member, when appointed by the governor, will take office on July 1, of that year.

If you are interested in becoming a candidate for this position or have any questions, please contact the Board office.

It Is Flu Season: Important Legal Requirements from the Pharmacist-Administered State Influenza Protocol

The pharmacist must meet these qualifications:

1. Currently licensed in good standing,
2. Hold current Basic Life Support training,
3. Completion of an Accreditation Council for Pharmacy Education-approved immunization course,
4. Completion of at least one hour of approved continuing education covering influenza vaccine administration, and
5. Have liability insurance covering vaccine administration.

Under this protocol, the age restriction is 18 years and older for those receiving the vaccine. Pharmacists must follow proper sterile technique and gloving procedures when preparing vaccine for administration. Needles must not be recapped before they are placed in the safety container. Pharmacists who are vaccinating are required to receive a hepatitis B vaccine series or have demonstrated proof of immunity. Pharmacists must be aware and prepared to handle adverse events on the chance that an adverse reaction to the vaccine occurs.

Pharmacies Administering Vaccines by State Protocol Are Required to Have the Following Materials on Hand

♦ A current copy of the “South Carolina Board of Medical Examiners Protocol for Administration of Influenza Vaccine by Pharmacists.”
♦ A supply of the most current federal Vaccine Information Statements for influenza vaccines or electronic access to these statements.
♦ Aqueous epinephrine USP (1:1000), in ampules, vials of solution, or pre-filled devices (ie, EpiPen®). If an EpiPen is to be stocked, at least three adult EpiPens (delivering a single dose of 0.3 mg/0.3 mL) should be available.
♦ Diphenhydramine (Benadryl®) injectable solution (50 mg/mL) and oral 25 or 50 mg tablets.
♦ Syringes: 1 mL and 3 mL, 22 g and 25 g, 1 inch, 1½ inch, and 2 inch needles for epinephrine and diphenhydramine.
♦ Alcohol swabs and bandages.
♦ Blood pressure monitoring device or stethoscope and sphygmomanometer (with adult and extra-large cuffs).
♦ Adult-size pocket mask with one-way valve.
♦ Flashlight with extra batteries (for examination of mouth and throat).
♦ Wrist watch with ability to count seconds.
♦ Telephone access.
♦ Equipment to enable the vaccinee to sit or lie down if he or she experiences an adverse reaction to the vaccine.
♦ A container to safely dispose of the used needles. It must comply with standards.

The protocol can be found on the Board Web site.

Board Meeting Agenda

At its September meeting, the Board voted to close the agenda two weeks prior to scheduled meeting dates. This change is to give the Board members adequate time to review the Board meeting materials prior to the meeting. Requests to appear before the Board with support documents should be submitted by this deadline. Agendas for meetings will be closed and then posted on the Board Web site two weeks prior to the meeting date.
Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 0 536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA’s MedWatch Program. More information about this recall is available on the FDA Web site at www.fda.gov/Safety/Recalls/ucm357909.

Barcoding Technology for Community Pharmacy

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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.

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 2006 study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for not implementing barcode scanning for product verification, other than cost, included uncertainty regarding the “right” vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy’s readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies. Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at www.ismp.org/AHRQ/Default.aspx?link=sa.


ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new ISMP Medication Safety Alert! publication, Long-Term Care Advise-ERR, as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With ISMP Medication Safety Alert! publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at www.ismp.org/newsletters/longtermcare.
FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen.

“This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications,” said Sharon Hertz, MD, deputy director of FDA’s Division of Anesthesia, Analgesia, and Addiction Products. “However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal.” The full consumer update is available on the FDA Web site at www.fda.gov/ForConsumers/Consumer Updates/ucm363010.htm.

Reminder to Purchase Drugs Only from Licensed Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP’s VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit www.nabp.net/programs/accreditation/vawd.

Voluntary Recall of Expiired Sterile Products

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians’ offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of “health care provider,” and thus may not obtain NPI numbers. The clarification also states that “Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently.” CMS also notes that “if a veterinarian fulfills the definition of ‘health care provider’ in a profession other than furnishing veterinary services,” such as if they are also a nurse practitioner, “the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI.”

Don’t Miss Out on Valuable CPE Credit.

Pharmacists & Technicians:

Register for CPE Monitor Today!

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.
Update on SCRIPTS, the Prescription Monitoring Program

By Christie Frick, RPh, PMP Director

The South Carolina Department of Health and Environmental Control (SC DHEC) prescription monitoring program (PMP), South Carolina Reporting & Identification Prescription Tracking System (SCRIPTS), would like to make you aware of upcoming changes. First, the DHEC would encourage all pharmacists to register to become users of the SC PMP. The program contains more than 56 million records and offers invaluable information as an additional tool for your professional use. Registration instructions can be found at www.dhec.sc.gov/scripts.

Additionally, the DHEC is planning to upgrade from American Society for Automation in Pharmacy (ASAP) 95 to ASAP 4.2 early next year. Please contact your software vendor to make them aware of this change. You will receive specific timetables as they become available. To complement this upgrade, the DHEC will require more frequent uploading. You are encouraged to begin increasing the frequency of your uploads now to ease the transition and to enhance the usefulness of the data to users that rely on the most comprehensive prescription dispensations.

The DHEC appreciates your support of SCRIPTS and welcomes any feedback or suggestions. Please feel free to contact the DHEC at 803/896-0688 or at scripts@dhec.sc.gov.

Compliance Tips
Consultant Pharmacist Written Monthly Inspections

Upon routine inspections of non-dispensing drug outlets, Board staff has discovered fraudulent activity regarding the use of photo/fax copies in place of the original during the written monthly inspection. According to §40-43-86(C)(1)(f), the consultant pharmacist must perform written monthly inspections that are readily available. This is notice that the original must be kept at the site upon each monthly inspection. Staff recommends that consultants make a copy of the monthly report to retain for their records should any discrepancies arise.

Other required duties of the consultant pharmacist include establishing policies and procedures for the procurement, storage, and distribution of drugs; establishing and supervising the record keeping system for the purchase, sale, possession, storage, safekeeping, and return of drugs; facilitating drug recalls, the removal of outdated and adulterated drugs, and acting as a drug information resource for the staff; and being available by phone for questions.

Clarification on Taking Verbal Orders for Controls

By SC DHEC Bureau of Drug Control

According to §40-43-82(C)(1) of the South Carolina Pharmacy Practice Act, a supervising pharmacist may authorize a state-certified pharmacy technician to receive and initiate verbal telephone orders. However, §44-53-360(b) of the South Carolina Code of Laws specifically states, “a pharmacist may dispense a controlled substance included in Schedule III, IV, or V pursuant to either a written prescription signed by a practitioner, or a facsimile of a written, signed prescription, transmitted by the practitioner or the practitioner’s agent to the pharmacy, or pursuant to an oral prescription, reduced promptly to writing and filed by the pharmacist.” Therefore, state-certified pharmacy technicians are not allowed to take verbal orders for controlled substances (CS).

Clarification on Identification Requirements for Dispensing CS

By SC DHEC Bureau of Drug Control

The Bureau of Drug Control has been asked to clarify the identification requirements for dispensing a CS. §44-53-360(i) states:

Excepting a mail order prescription dispensed in compliance with Chapter 43 of Title 40 for which the dispenser requires proper identification of the recipient, a prescription for a controlled substance in Schedules II through V may not be filled unless the dispenser knows the recipient or requires the recipient to produce a government issued photo identification, and the dispenser notes the identification source and number on the prescription, or in a readily retrievable log including:

(1) prescription number;
(2) date prescription filled;
(3) number and type of identification;
(4) initials of person obtaining and recording information.

A government-issued photo identification (ID) could include a state-issued ID or driver’s license, valid passport, military ID, or concealed weapons permit.

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