August 2012

News

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

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Update Your Congressional District with the Board

With the recent redistricting of the congressional districts in South Carolina, please verify which congressional district you live in by visiting *https://info.scvotes.sc.gov/eng/voterinquiry/VoterInformationRequest.aspx?PageMode=VoterInfo*. Once you have verified your district, go to the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy Web site to update your congressional district. Please follow these instructions. Go to *www.llronline.com/pol/pharmacy*. On the left-hand side, choose "Change Your Address" to go to Online Services. In the Online Services section, choose "Change of Address," and log in using your ID and password. Then click on "Proceed." Next, click on "Main & Mailing Address Update." If you have more than one license with the Department of Labor, Licensing, and Regulation, you must change your address for each licensing board.

New Seventh Congressional District Results in Board Elections

The **Seventh Congressional** Board of Pharmacy member term begins July 1, 2012, and ends June 30, 2018. Any pharmacist interested in running as a candidate must:

- Reside in the Seventh Congressional District;
- Be licensed and actively practicing pharmacy in South Carolina; and
- Before September 15, 2012, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the Seventh Congressional District.

After receiving biographies and petitions, the Board administrator will:

- Prepare and mail ballots by October 15, 2012, to all pharmacists who have notified the Board they reside in the Seventh Congressional District; and
- Certify as true and valid all ballots postmarked before November 15, 2012, and received by the Board office before November 25, 2012.

The Board of Pharmacy will conduct an election for the **Sixth Congressional** District seat, which expires June 30, 2018, due to the fact that the candidates that ran for this seat previously are now in the Seventh Congressional District. Any pharmacist interested in running as a candidate must:

- Reside in the Sixth Congressional District;
- Be licensed and actively practicing pharmacy in South Carolina; and
- Before September 15, 2012, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the Sixth Congressional District.

After receiving biographies and petitions, the Board administrator will:

- Prepare and mail ballots by October 15, 2012, to all pharmacists who have notified the Board they reside in the Sixth Congressional District; and
- Certify as true and valid all ballots postmarked before November 15, 2012, and received by the Board office before November 25, 2012.

The Board of Pharmacy will conduct an election for the **Fifth Congressional** District seat, which expires June 30, 2013. Any pharmacist interested in running as a candidate must:

- Reside in the Fifth Congressional District;
- Be licensed and actively practicing pharmacy in South Carolina; and
- Before September 15, 2012, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the Fifth Congressional District.

After receiving biographies and petitions, the Board administrator will:

- Prepare and mail ballots by October 15, 2012, to all pharmacists who have notified the Board they reside in the Fifth Congressional District; and
- Certify as true and valid all ballots postmarked before November 15, 2012, and received by the Board office before November 25, 2012.

The Board of Pharmacy will conduct an election for the **Fourth Congressional** District seat, which expires June 30, 2014. Any pharmacist interested in running as a candidate must:

- Reside in the Fourth Congressional District;
- Be licensed and actively practicing pharmacy in South Carolina; and
- Before September 15, 2012, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the Fourth Congressional District.

After receiving biographies and petitions, the Board administrator will:

- Prepare and mail ballots by October 15, 2012, 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 November 15, 2012, and received by the Board office before November 25, 2012.

The Board will certify to the governor, in writing, the names of the three candidates receiving the most votes in the election for each district and send the name of the person each nominee is replacing on the Board.

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

Board Elections

At the June 2012 meeting, the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy members elected

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FDA Warned Medical Practices About Counterfeits in US and Risks to Patients

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.*

Rethink the Vial

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.*

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid prescriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request *Parents' Guide to Understanding Prescription Drug Abuse* brochures for distribution to your patients, visit *www.SafeguardMyMeds.org.*

Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at *www.abbott.com/vicodin-consumer-alert.htm.* Abbott advises that anyone who has the counterfeit ver-

sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at *www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.*

PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at *www.safemedicines.org/resources-for-healthcare-professionals.html*. Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm.* Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at *www.fda.gov/Drugs/DrugSafety/ucm300747.htm.* Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWAR$_X$E® Web site at *www.awarerx.org/informedSiteMap.php.*

Providers Asked to Advise Patients of Acetaminophen Safe Use Steps

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWAR$_X$E Web site at *www.awarerx.org/OTCMedUse.php.* The AWAR$_X$E consumer protection program and the National Association of Boards of Pharmacy® (NABP®) are part of the Acetaminophen Awareness Coalition.

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Joseph D. Bushardt, Jr, RPh, of Lake City, SC, as the new chairperson. Bushardt is the pharmacist representing the Sixth Congressional District. **Dock Henry Rose, RPh,** of Greer, SC, representing the Fourth Congressional District, was elected as vice chairperson. Each will serve a one-year term from July 1, 2012 until June 30, 2013.

New Inspection Software

As of June 21, 2012, the Board's pharmacist inspectors are using a new computer software program to document the Final Inspection Report. The new software allows the Final Inspection Report to be e-mailed directly to the appropriate person or persons. If the responsible person does not have an e-mail address to receive the report, it may be sent to a district manager or a personal e-mail address.

Once the Final Inspection Report is received by e-mail, it should be kept on file for a minimum of two years. If there are any violations noted on the Final Inspection Report, it is the responsibility of the pharmacist-in-charge or Permit Holder to respond by e-mail or in writing to the inspector within the number of days specified on the Final Inspection Report. The inspector's name and e-mail address will be on the Final Inspection Report.

Copies of the guidelines used by inspectors for each type of inspection are on the Board of Pharmacy Web site at the bottom of the page under the Applications/Forms section. The inspector may use more than one inspection type during the inspection process. Examples include Retail/Nonsterile, Retail/Nuclear/Sterile, Institutional/Sterile, or any combination that meets the operations of the facility.

Transferring On-Hold Electronic Prescriptions

At the June 2012 meeting, the Board of Pharmacy agreed to allow non-controlled electronic prescriptions on hold to be transferred if the electronic prescription is assigned a prescription number at the time it is accepted at the pharmacy. This will allow the prescription to be tracked back to the original pharmacy.

CPE Monitor

The National Association of Boards of Pharmacy® (NABP®), in collaboration with the Accreditation Council for Pharmacy Education (ACPE), and ACPE providers, has launched a continuing pharmacy education (CPE) monitoring service, known as CPE Monitor™. All pharmacists and pharmacy technicians should register for this valuable electronic service. There is no charge to use this service for tracking ACPE-accredited CPE hours earned. It is anticipated that beginning in 2013, all ACPE-accredited providers will require licensees to submit their NABP e-Profile ID, which is obtained when an individual creates an e-Profile and registers for CPE Monitor, in order to obtain CPE credit. So do not delay in signing up. Registration and additional information about CPE Monitor may be found by visiting *www.MyCPEmonitor.net.*

Compliance Tips

1. **Address Change:** Any currently licensed pharmacist, pharmacy technician, or pharmacy intern, who changes his or her mailing address, must notify the Board in writing within 10 days, listing his or her name, license or registration number, and new mailing address.
2. **Employment Changes:** When a licensed pharmacist, technician, or intern changes employment, he or she must notify the Board in writing within 10 days of the change, giving the name, address, and permit number of the permitted facility at which he or she was last employed and the name, address, and permit number of the expected future employer.
3. **Permit Holder Reporting Requirements:** All permit holders must report to the Board of Pharmacy within 10 working days of the discovery of the occurrence of any of the following: permanent closing; change of ownership, management, location, consultant pharmacists, or pharmacist-in-charge of a pharmacy; change in employment of pharmacists or pharmacy technicians within a pharmacy permitted by the Board; and disasters, accidents, destruction, or loss of records required to be maintained by state or federal law. Upon closing, the permittee must return the permit to the Board within 30 days.
4. **New Permit Required:** New permits are required for any change of ownership, change of pharmacy name, or change of location from one city to another. Permits are **not transferable,** and each location requires its own permit. Correctly completed applications for new permits or changes to existing permits must be received in the Board of Pharmacy office at least 45 days before the opening date of the facility or effective date of a change. An on-site inspection is required before a permit will be issued.
5. **Pharmacy Technician Continuing Education:** Pharmacy technicians are **not** exempt from completing mandatory continuing education credits during their first year of registration with the Board.

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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