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News

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

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Kingstree Bldg, 110 Centerview Dr • PO Box 11927 • Columbia, SC 29211-1927
www.llr.state.sc.us/pol/pharmacy • 803/896-4700

Congratulations to Board Appointee

The South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy would like to congratulate J. Addison Livingston, PharmD, RPh, of Swansea, SC, on his recent reappointment to the Board by Governor Nikki Haley.

Livingston's six-year term expires on June 30, 2021. He represents the Second Congressional District. He will continue to provide valuable expertise in compounding, consultant, and independent community pharmacy practice settings. The Board would like to extend its gratitude to Dr Livingston for his continued hard work and commitment to the citizens of South Carolina and the profession of pharmacy.

Upcoming Board Vacancy

If you live in the Third Congressional District and are interested in serving on the Board, you must meet the following requirements:

- Reside in the Third Congressional District;
- Be licensed and actively practicing pharmacy in South Carolina; and
- Before December 1, 2015, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the Third Congressional District. The term begins July 1, 2016, and ends June 30, 2022.

After receiving biographies and petitions, the Board administrator will:

- Prepare and mail ballots by January 15, 2016, to all pharmacists who have notified the Board that they reside in the Third Congressional District; and
- Certify as true and valid all ballots postmarked before February 15, 2016, and received by the Board office before February 25, 2016.

Before March 1, 2016, 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 whom 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.

New Regulations on Administrative Citations, Penalties, and Fines Pass

Regulations 99-45 and 99-46 passed on June 26, 2015. The Board is utilizing the administrative citations and penalties process in lieu of possible disciplinary actions. However, failure to correct violations or pay a citation may subject the entity and/or the individual to discipline under §40-43-140(A)(1)(a). For your reference, the regulations are listed below.

Regulation 99-45. Administrative Citations and Penalties

A. The board may issue administrative citations and cease and desist orders in person, or by certified mail, and may assess administrative penalties against an entity or individual for the violations listed below. If the licensee is working at his or her primary place of employment listed with the Board, the licensee must have his or her license or registration displayed. If the licensee is not working at his or her primary place of employment, the licensee must have a wallet card available for inspection. The citation must be signed by the Chief Drug Inspector.

1. Failure to Display Permit (Pharmacist-in-Charge [PIC]): $50
2. Failure to Display License or Possess Wallet Card: $100
3. Failure to Display Intern Certificate or Possess Wallet Card (PIC and Intern): $25
4. Failure to Display Pharmacy Technician Registration or Possess Wallet Card: $25
5. Pharmacy Technician Working Without Registration (Permit Holder): $500
6. Pharmacy Technician Working Without Registration (PIC): $500
7. Pharmacy Technician Working With Lapsed Registration (Permit Holder): $500
8. Pharmacy Technician Working With Lapsed Registration (PIC): $500

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FDA Issues Warning About Name Confusion for Brintellix and Brilinta

Due to similar brand names, there have been incidents where the antidepressant Brintellix® (vortioxetine) and the anti-blood clotting medication Brilinta® (ticagrelor) have been confused, resulting in prescribing and dispensing errors, warns Food and Drug Administration (FDA). The agency notes that no reports indicate that a patient has ingested the wrong medication; however, reports of prescribing and dispensing errors continue. FDA recommends that health care providers include the generic name of the medication in addition to the brand name, as well as the indication for use when prescribing these medications. Patients are advised to check their prescriptions to ensure that the correct medication was dispensed. More information is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm.*

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

This is part two of a three-part series on seven persistent safety gaffes of 2014.

3) Vaccine Errors: Repetitive Errors Reported in the Last Decade

How often do DTaP (diphtheria and tetanus toxoids, and acellular pertussis) and Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccine mix-ups need to occur before regulatory action is taken to prevent confusion? Whatever the number, we can say that health care providers have probably met that threshold! Yet, vaccine errors like this continue to occur at an alarming rate (based on those reported to ISMP alone). Vaccine mix-ups occur often because of age-dependent formulations of the same vaccine, similar vaccine abbreviations, similar vaccine containers and labels, and storage near each other. Confusion between the diluent and vaccine has led to administration of the diluent alone or use of the wrong diluent. With an unfortunate rise in parents choosing not to vaccinate their children or themselves, health care providers cannot continue to make errors when vaccinating those who choose to be immunized; the impact on both individual and community immunity may be far-reaching.

4) Wrong Patient Errors: Not Opening the Bag at the Point of Sale

Community pharmacies are vulnerable to dispensing correctly filled prescriptions to the wrong patient at the point of sale, a risk that is well substantiated in the literature. This error is not influenced by the attributes of a specific medication; thus, dispensing any prescription medication to the wrong patient at the point of sale carries a similar level of risk. Based on an ISMP study, the error happens frequently at an estimated rate of 1.22 per 1,000 prescriptions. Among approximately 56,000 community pharmacies in the United States, this error rate suggests that 332,755 prescriptions will be dispensed to the wrong patient each month, or about six every month per pharmacy. One of the most effective ways to prevent this error is to open the bag of filled prescriptions at the point of sale to verify that the medications are for the correct patient. According to the ISMP study, this simple step reduces the risk of error by 56%, yet few pharmacies follow this practice.

5) Disrespectful Behavior: A History of Tolerance in Health Care

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and allowed to exist. Health care providers tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey conducted in 2003 clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey conducted a decade later demonstrates little progress. Disrespect diminishes a person's ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

FDA Advises Caution Against Codeine for Treating Colds in Young Patients

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds, and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at *www.fda.govSafety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm.*

Daytrana Patch May Cause Permanent Skin Color Changes, FDA Warns

In June 2015, FDA warned health care providers and consumers that Daytrana®, a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color as a result of repeated exposure to specific chemical compounds, according to an FDA safety alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in the FDA safety alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm.*

FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke

The labels of certain non-steroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm* provides more details.

Baxter International, Inc, Recalls Three Lots of IV Solutions Due to Particulate Matter

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous (IV) solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, lot numbers P319921 and P327635, which were distributed to US customers between October 7, 2014, and July 14, 2015. Additional information is available in an FDA press release at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm.*

Baxter also voluntarily recalled one lot of IV solution to the hospital/user level because of the potential for leaking containers, particulate matter, and missing port protectors. This recall affects 0.9% sodium chloride injection, USP (AUTO-C) with lot number C964601 (National Drug Code 0338-0049-03; expiration date: April 30, 2016). This recalled lot was distributed to customers and distributors nationwide between January 22, 2015, and February 12, 2015. Leaking containers, particulate matter, and missing port protectors could result in contamination of the solution and, if not detected, could lead to a bloodstream infection or other serious adverse health consequences, explains FDA. The agency notes further that "injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs." More information about this recall is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm.*

FDA Warns Against Unapproved Prescription Ear Drops

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval, and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- benzocaine;
- benzocaine and antipyrine;
- benzocaine, antipyrine, and zinc acetate;
- benzocaine, chloroxylenol, and hydrocortisone;
- chloroxylenol and pramoxine; and
- chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm.*

Acino Products in New Jersey Ordered to Stop Selling Rectacort-HC and GRx HiCort 25

Under the direction of FDA, a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in its possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm.*

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

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9. Pharmacy Technician Working With Lapsed Registration (Technician): $50
10. Pharmacy Operating with greater than 3:1 Technician to Pharmacist Ratio (PIC) [§40-43-86(B)(4)(b)]: $500
11. Pharmacy Operating with greater than 3:1 Technician to Pharmacist Ratio (Permit Holder) [§40-43-86(B)(4)(b)]: $500
12. Failure to Notify Board of Facility Relocation: $100
13. Failure to Notify Board of PIC Change: $100
14. Flu Protocol—Technical Violation: $500
15. Failure to Notify Board of Change in Ownership: $100

B. Separate citations and administrative penalties may be assessed for each violation.

C. Administrative citations authorized under this section are separate from, and in addition to, all other remedies, either civil or criminal.

D. A licensee assessed an administrative citation may appeal the citation to the board within thirty (30) calendar days of the receipt of the citation. If an appeal is filed, the department shall schedule a hearing before the board or its designee for a final determination on the matter. If no appeal is filed, the citation is deemed a final administrative order, and penalties are due within ninety calendar days of receipt of the citation, or other written demand.

E. Extensions to pay citations must be submitted in writing, and will be at the discretion of the Chairman.

F. Failure to pay a citation is considered a violation of this regulation, and may subject the entity to discipline under S.C. Code Ann. § 40-43-140(A)(1)(a).

G. Should a licensee or permittee receive one or more administrative violations of the same type in a five year period, any subsequent violation(s) must be referred to the board for disciplinary action.

99-46. Fines.

A. Upon determination by the board that one or more grounds for disciplining a licensee or permittee exists, the board may impose a fine of $500 per violation, not to exceed a total amount of $25,000 total per action, plus the costs of the disciplinary action. Fines are payable immediately upon the effective date of discipline unless otherwise provided by the board. Interest accrues after the fines are due at the maximum rate allowed by law. No licensee or permittee against whom a fine is levied is eligible for reinstatement until the fine has been paid in full.

B. An individual who has been found by the board to have unlawfully engaged in the practice of pharmacy under S.C. Code Ann. § 40-43-160(A) may be fined in an amount not to exceed $25,000.

Immunization Expansion Law Signed

Governor Haley signed the immunization expansion legislation into law on June 1, 2015. The new law was published in the Board of Pharmacy's August 2015 *Newsletter.* The Joint Pharmacist Administered Vaccines Committee has convened and is developing proposed written protocols for the purpose of authorizing pharmacists to administer vaccines without an order or prescription of a practitioner as authorized by §40-43-190. The committee was required to submit its initial recommendations to the South Carolina Board of Medical Examiners by October 1, 2015.

The only protocol approved by the Board of Medical Examiners at this time is the **"Protocol for Administration of Influenza Vaccine by Pharmacists"** currently posted on the Board of Pharmacy website, *www.llr.state.sc.us/pol/pharmacy*. Board staff has received many calls in reference to the revised law and the approved protocols. Once the Board of Medical Examiners approves other specific vaccines in the written protocol, it will be posted on the Board of Pharmacy website.

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