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West Virginia Board of Pharmacy News

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Another Reminder Concerning Registration of PTTs and PTs

Under the old rules and process for hiring a pharmacy technician trainee (PTT), in order for that new PTT to start work in a pharmacy, the pharmacist-in-charge (PIC) simply needed to fill out a notice form indicating the new employee's name and start date in the old two-year/2,080-hour training program. Now the new rules require that an application and background check be filed with the West Virginia Board of Pharmacy for a PTT, and then that application must be approved and the PTT must be issued a registration by the Board prior to beginning work in any pharmacy as a technician. This applies whether the person is going to a community or technical college or other learning institution-based training program, or has been hired by a pharmacy to undergo the new 15-month/960-hour on-the-job training. (Within three months from the completion of either training, in order to continue working as a PTT while undergoing national certification examinations, the PTT must file his or her application to become a West Virginia registered pharmacy technician (PT) and receive his or her PT registration.)

In shifting from the old rules to the new, the Board has encountered more than a few instances in which "PTTs" were already working without registration. In short, they are not lawful PTTs until registered, and it is a violation for them to begin working before that time. Similarly, the Board has been finding a number of situations in which a PTT started under the old system, but no notice of start date can be located at the Board or the pharmacy, or a PTT started more than two years ago in the old two-year/2,080-hour program, but never tested and registered as a PT. Those are also violations. Hopefully, as the old requirements are filtered out of the system and everyone complies with the new statute and rules, the Board will not see any more instances of a PTT having to petition the Board asking whether or not it will give credit for hours worked without being properly registered with the Board, and the Board having to investigate for potential discipline for these violations.

Another issue the Board is encountering is with regard to PT candidates who worked as a PT in another state and are now moving to West Virginia. West Virginia does not currently have reciprocity for PTs, as training and registration requirements vary from state to state. The statute and rules require that, to work as a PT in this state, one must be properly registered in this state; being registered in another state does not qualify one to work as a registrant in this state. In this same vein, national certification, while required, is not registration; registration is a separate step. So, in order to be registered as a PT, one must, among other things, be able to prove that he or she has either (a) graduated from a learning institution-based PT education and training program that has been approved by the Board; or (b) completed a pharmacy-provided PT education and training program that has been approved by the Board. So, if a PT is coming from out-of-state and cannot provide this proof, he or she would simply have to be hired in as a PTT and undergo the 15-month/960-hour training program to ensure that he or she has received the training required by West Virginia law.

Inspectors Provided Information at WVPA 108th Annual Convention

Inspectors Buck Selby and Roger Shallis attended the West Virginia Pharmacists Association (WVPA) 108th Annual Convention and were permitted to set up a display on behalf of the Board. Among other things, they provided information on inspections and issues with controlled substance (CS) prescriptions, and made themselves available to answer questions. This was a great piece of outreach on behalf of the Board by these inspectors. Many thanks go to WVPA for welcoming them and permitting them to make this display (see picture of display on page 4 of this *Newsletter)*.

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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.*

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Pictured: Board table display. The second sign from the left reads: WE'RE FROM THE GOVERNMENT/WE'RE HERE TO HELP

Tips for CPE Records to Help Both Your Inspector and PIC Make Inspections Go Smoothly and Quickly

Here is a tip for all pharmacists regarding your continuing pharmacy education (CPE) records that inspectors indicate will save time and make inspections quicker to complete, thus making them a bit less intrusive into the workday of the pharmacy staff. West Virginia Code §30-1-7a, applicable to all professional licensing boards, requires each board to require continuing education as a prerequisite to license renewal (including the requirement for all prescribers and dispensers of CS to have a course " . . . on the subject of drug diversion training, best-practice prescribing of controlled substances training[,] and prescribing and administration of an opioid antagonist training" in order to be eligible for renewal of their licenses, and for recent graduates to complete that course in the first year after graduation and each renewal period thereafter). West Virginia Code of State Rules Title 15, Series 3, contains the CPE requirements for pharmacists, including the requirement of a minimum of 30 hours per renewal period, three hours of which must be West Virginia drug diversion training. When inspecting pharmacies and other places holding a Board authorization (such as a nursing home or other place with a CS handling permit), the inspectors audit the pharmacists' CPE records to ensure compliance. To aid in this review of individual CPE records, the inspectors recommend that each pharmacist leave a printed copy of his or her National Association of Boards of Pharmacy® CPE Monitor® report, showing the CPE records associated with the most recent license renewal, with the PIC of every pharmacy in which he or she works a shift. That way, the PIC does not have to search through the CPE records, and the inspector is presented with a one- or two-page document that shows all the information on CPE for your latest license renewal. Of course, any CPE that is not reflected on the CPE Monitor report, such as the required West Virginia drug diversion training, will need to be documented separately, and it will help to attach proof of attendance of those to the report as well. What could be a 10-minute review of each pharmacist's CPE records can then be accomplished in less than a minute.

On a separate but related note, even if you are an out-of-state pharmacist and sign your renewal application indicating that you have complied with the CPE requirements of the state in which you practice, you must be sure that you are getting the latest three-hour training on drug diversion and West Virginia statistics, which is a current requirement for each and every renewal.

To print a copy of your CPE Monitor report, you must complete the following steps: Visit *https://store.nabp.net/OA_HTML/xxnabpibeGblLogin.jsp* and sign in using your login name and password. Click on the CPE Monitor link on the upper left-hand area of the website. In the Search by Activity Date field, enter the starting month and ending month. Click on "Search" and then click on "Print Transcript of CE Activity." Do this for the period covering your **existing** license renewal year. Thanks for your help making inspections a bit easier on all involved.

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