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Virginia Board of Pharmacy News

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Board Election of Vice Chairman

Congratulations to Rebecca Thornbury, who was elected vice chairman of the Virginia Board of Pharmacy at the September full Board meeting. Ms Thornbury will serve in this position until June 30, 2016.

A list of current Board members and officers may be accessed at *www.dhp.virginia.gov/pharmacy/pharmacy_board.htm*.

Reminder for 2015 CE Requirement on Opioid Use or Abuse

Pursuant to §54.1-3314.1(J), and to address concerns with prescription drug abuse, the Board is requiring all pharmacists to obtain at least one hour of continuing education (CE) in the subject of "opioid use or abuse" during the calendar year of 2015. The one-hour minimum requirement is part of the required 15 hours of CE that must be obtained during 2015, and not in addition to the required 15 hours. This is a one-time requirement; further action of the Board would be required to mandate CE in a specific topic in future years. This requirement applies only to pharmacists, not pharmacy technicians. Please note that the requirement does not specify particular objectives that must be included in the program, nor does it identify a list of approved programs. The general requirement is of a broad nature in order to allow pharmacists the flexibility in choosing an appropriate CE program that focuses on the use or abuse of opioids. The CE must be obtained between January 1 and December 31, 2015.

Clarification of Zero Reports Within CQI Requirements

Board staff has received communication from the Institute for Safe Medication Practices (ISMP) that several pharmacists in Virginia have been submitting zero reports to this patient safety organization (PSO) believing that doing so is required in regulation. Please note that a pharmacy is not required to report to a PSO that no dispensing errors have occurred. Subsection A of Regulation 18VAC110-20-418 states that a record indicating the date a report was submitted to a PSO shall be maintained by the pharmacy for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record maintained by the pharmacy. The zero report should not be submitted to ISMP or any other PSO unless the pharmacy has engaged the PSO to monitor the pharmacy's rate of dispensing errors and the PSO has requested submission of this information.

For more information on requirements for continuous quality improvement (CQI) programs, refer to §54.1-3434.03 of the Virginia Drug Control Act and Regulations 18VAC110-20-10 and 18VAC110-20-418.

Notification Requirements for Name and Address Changes

Subsection B of §54.1-2400.02 of the Code of Virginia requires the Virginia Department of Health Professions (DHP) to collect an official address of record from each health professional to be used by DHP for agency purposes. Subsection C of §54.1-2400.02 also requires DHP to provide an opportunity for a licensee to provide a second address for the purpose of public dissemination. If the licensee or registrant does not provide a second (public) address, the official address of record will be used as the public address for the purpose of public dissemination. If the licensee or registrant would prefer that his or her address of record remain confidential, then an alternative public address must be provided to DHP. (Note: The License Lookup feature on the Board's website at *https://dhp.virginiainteractive.org/Lookup/Index* does not list the licensee's street address; it only lists the city and state of the licensee's address. However, public addresses are available through Virginia Interactive at *https://dhp.virginiainteractive.org/Home/SDownloadInfo.)* An individual (ie, pharmacist,

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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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pharmacy technician, or pharmacy intern) is not required to submit a place of residence for either the official address of record or the public address. A post office box or the address of a practice location is acceptable for an individual's license or registration.

Any change in the official address of record for a pharmacist, pharmacy technician, or pharmacy intern must be submitted to the Board in writing or electronically within 14 days of the change, per Regulations 18VAC110-20-40, 18VAC110-20-80, and 18VAC110-20-104. Additionally, Regulation 18VAC110-20-21 requires a licensee or registrant to notify the Board in writing if there is a change in the public address provided. A pharmacist, pharmacy technician, or pharmacy intern may change his or her official address of record through the Online Licensing feature at *www.dhp.virginia.gov/mylicense/renewalintro.asp*. Simply log in as a new or returning user and click on "Change Address of Record." Alternatively, an individual may submit written notification to the Board via mail, facsimile, or email indicating the change in the official address of record. To update a change in the public address, an individual may complete this change online when renewing his or her license or registration, or the individual may provide this information to the Board in writing via mail, facsimile, or email specifically indicating that the request is intended for the public address.

When a pharmacist, pharmacy technician, or pharmacy intern has a change in name, the individual may update his or her name by submitting written notification to the Board via mail, facsimile, or email. The notification must include his or her license number, a copy of a marriage certificate or other court order legally authorizing the name change, and any preference for how the name should appear on the license or registration. The licensee or registrant should receive an updated license or registration within seven to 10 business days following processing. A licensee or registrant may not change his or her name via the Online Licensing feature.

Requesting Licensure Verification or Duplicates of License

Subsection H of Regulation 18VAC110-20-20 now authorizes the Board to charge a nominal administrative fee of $10 for a duplicate license or registration and $25 for verification of licensure or registration. Requesting a duplicate copy of a pharmacist license, pharmacy technician registration, or pharmacy intern registration may now be completed online through the Online Licensing system at *www.dhp.virginia.gov/mylicense/renewalintro.asp*. Simply log in as a new or returning user, verify the address of record, and submit payment of $10 via credit card; a duplicate license or registration will be mailed to the address of record within seven to 10 business days. For verification of licensure or registration, please note that the online License Lookup feature at *https://dhp.virginiainteractive.org/Lookup/Index* serves as primary source verification and, with the exception of high-volume users of the system, is available free of charge. Alternatively, a request for licensure verification may be completed by submitting the licensure verification request form found at *www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm*, along with a check or money order for $25 made payable to the Treasurer of Virginia. A separate form must be submitted for each verification request.

Reporting Requirements for an Unusual or Significant Loss of Drugs

The Drug Control Act in §54.1-3404 requires a registrant or licensee who discovers a theft or any other unusual loss of a drug in Schedules II, III, IV, or V to immediately report the theft or loss to the Board. Similarly, Title 21 Code of Federal Regulations (CFR) §1301.74 states, "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss." In addition to the notification requirement, a registrant or licensee must furnish the Board with a listing of the kind, quantity, and strength of such drugs lost within 30 days after the discovery of the loss. Submission of a copy of Drug Enforcement Administration (DEA) Form 106 is acceptable for complying with the Board's reporting requirement.

While it is clear that a "theft" of any quantity of drug in Schedules II-V must be reported to the Board and DEA, there is occasionally confusion regarding the reporting requirements for a loss when it is unclear whether the loss constitutes an "unusual" or "significant" loss. While the terms "unusual loss" as used in the Drug Control Act and "significant loss" as used in the federal regulation are not defined in state or federal rules, DEA does offer guidance in rule and the *Pharmacist's Manual* for determining if a loss constitutes a "significant loss." It is suggested that pharmacists and pharmacy technicians follow DEA's guidance for satisfying the state and federal reporting requirements for both unusual and significant drug losses. To determine whether a loss is "significant," Title 21 CFR §1301.74 states:

> . . . a registrant should consider, among others, the following factors:
>
> 1. The actual quantity of controlled substances lost in relation to the type of business;
> 2. The specific controlled substances lost;
> 3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique

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activities that may take place involving the controlled substances;

4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
5. Whether the specific controlled substances are likely candidates for diversion;
6. Local trends and other indicators of the diversion potential of the missing controlled substance.

Furthermore, DEA's 2010 edition of the *Pharmacist's Manual* states:

> Although the [Controlled Substances Act] regulations do not define the term "significant loss," it is the responsibility of the registrant to use his/her best judgment to take appropriate action. Whether a "significant loss" has occurred depends, in large part, on the business of the pharmacy and the likelihood of a rational explanation for a particular occurrence. What would constitute a significant loss for a pharmacy may be viewed as comparatively insignificant for a hospital or manufacturer. Further, the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a registrant, which must be reported. The burden of responsibility is on the registrant to identify what is a significant loss and make the required report to DEA.

In accordance with §54.1-3404 of the Drug Control Act, if the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he or she shall immediately make a complete inventory of all Schedule II-V drugs. Also, if after the initial notification of a theft or loss to the Board or DEA the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, then a complete listing and the DEA Form 106 is not required to be filed. However, the licensee or registrant should notify the Board and DEA in writing of this fact in order to resolve the initial report.

If it is determined that a loss occurred, but it is not significant, DEA indicates in the *Pharmacist's Manual* that " . . . the registrant should place a record of the occurrence in a theft and loss file for future reference. Miscounts or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106, but rather should be noted in a separate log at the pharmacy management's discretion." Lastly, as indicated in the *Pharmacist's Manual* and supported by the Board, if there is a question as to whether a theft has occurred or a loss is significant, a licensee or registrant should err on the side of caution and report it to DEA and the Board.

Prescriptions Awaiting Delivery

In accordance with Regulation 18VAC110-20-200, prescriptions prepared for delivery to the patient may be placed in a secured area outside of the prescription department, not accessible to the public, where access to the prescriptions is restricted to individuals designated by the pharmacist. With the permission of the pharmacist, the prepared prescriptions may be transferred to the patient at a time when the pharmacist is not on duty. If a prescription is delivered at a time when the pharmacist is not on duty, written procedures shall be established and followed by the pharmacy that detail security of the dispensed prescriptions and a method of compliance with counseling requirements of §54.1-3319 of the Code of Virginia. Additionally, a log shall be made and maintained of all prescriptions delivered to a patient when a pharmacist is not present to include the patient's name, prescription number(s), date of delivery, and the signature of the person receiving the prescription. Such log shall be maintained for a period of one year.

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