October 2015

Minnesota Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

University Park Plaza • 2829 University Ave SE, Suite 530 • Minneapolis, MN 55414-3251
www.pharmacy.mn.gov

Disciplinary Actions

Due to space limitations, information on disciplinary actions will no longer be included in the *Minnesota Board of Pharmacy Newsletter*. A document that provides information about recent Board disciplinary actions can be found on the Board's website under the "Resources/FAQs" menu item.

Governor Dayton Makes Appointments to Board

On February 23, 2015, Governor Mark Dayton announced the reappointment of Stuart Williams and the appointment of Kurt Henn to the Board. Mr Williams is a public member who was reappointed to a second four-year term, which expires on January 7, 2019. Dr Henn is a pharmacist member who was appointed to a four-year term that expires on the same date. Dr Henn replaced Karen Bergrud, who decided not to seek reappointment to a third term. The Board thanks Ms Bergrud for her very capable service to the public.

On August 6, 2015, Governor Dayton announced the appointment of Joseph Stanek to the Board. Dr Stanek is a pharmacist member who was appointed to fill the remaining portion of a term that expires on January 4, 2016. Dr Stanek replaced Kay Hanson, who retired from the practice of pharmacy and was required to resign from the Board. Ms Hanson had served on the Board for over 11 years, and the Board also thanks her for her very capable service to the public.

Mr Williams, who currently serves as the Board's president, is an attorney with the Minneapolis law firm of Henson & Efron, P.A., where his practice includes business litigation and environmental law. He obtained his bachelor of arts and juris doctor degrees with honors from the University of North Carolina at Chapel Hill, and he served in the United States Army. Mr Williams formerly served as a public member on the Minnesota Nursing Board and the Minnesota Board of Psychology. He also formerly served on the Minnesota Lawyers Professional Responsibility Board, appointed by the Minnesota Supreme Court in 2007 and reappointed in 2010. In 2014, Mr Williams was appointed by the Minnesota Supreme Court to a four-year term on the Minnesota Client Security Board.

Dr Henn, of Wabasha, MN, has over 20 years of hospital pharmacy experience. Since June 1995, he has been the director of pharmacy at Saint Elizabeth's Medical Center, where he oversees operations of the inpatient and outpatient pharmacies. He also serves as the medical staff liaison at Saint Elizabeth's, and works as a staff pharmacist in the inpatient pharmacy on a regularly scheduled basis. Dr Henn attended the University of Minnesota College of Pharmacy and received his doctor of pharmacy degree in 1995.

Dr Stanek, of Plymouth, MN, has over 18 years of hospital pharmacy/sterile product production experience. Pharmacy positions he has held include pharmacy technician, staff pharmacist, clinical pharmacist, clinical coordinator, director of pharmacy, and his current position as program development manager for the Fairview Compounding Pharmacy. Dr Stanek received both bachelor of science and doctor of pharmacy degrees from Midwestern University.

Board Hires New Staff Member

During the 2015 Minnesota Legislative Session, the Board received an increase in its appropriation, part of which was for the purpose of creating a new legal analyst position. As a result of several factors, the Board has seen the number of complaints that need to be processed triple in recent years. Many of the additional complaints have been substantiated upon investigation, and have involved significant violations of statutes and rules that warrant disciplinary action. Brian Park, an attorney with 25 years of experience, was recently hired to fill this new position. Mr Park will assist in the investigation of certain types of complaints and will draft legal documents related to the disciplinary process. He may also assist in doing legal

continued on page 4

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.*

continued from page 1

research related to the drafting of proposed legislation and rules. Note that the Office of the Attorney General remains the Board's legal counsel.

Data Integrity and the Minnesota Prescription Monitoring Program

In order to be a reliable tool for prescribers and pharmacists, data in the Minnesota Prescription Monitoring Program (PMP) database must be complete and accurate. On a daily basis, Minnesota licensed pharmacies are required to upload data concerning dispensed controlled substance (CS) and butalbital prescriptions to the PMP database. When a pharmacy does not dispense any prescriptions for those drugs on a given business day, the pharmacy must still upload a "zero report."

Each pharmacy should have an individual identified as its "data uploader" who is responsible for reporting prescription data or zero reports to the PMP database. The uploader may be an individual at the corporate level who uploads data for multiple pharmacies (within the company), a software vendor, a pharmacy technician, a pharmacist, or whoever else is deemed to be responsible.

After each data upload, an "Edit/Error Report" is emailed or faxed to the individual identified as the uploader. The report lists prescriptions that, upon uploading, contained errors. Depending on the severity and number of errors, some prescriptions will upload even though they have "bad" data, while others will be rejected and not appear in the patient's PMP report. **Pharmacists and uploaders must work together to correct the errors and resubmit the data in a timely manner.** Failure to resubmit corrected data results in health care providers having an incomplete picture of their patients' CS history.

Examples of common errors include missing or invalid prescriber Drug Enforcement Administration (DEA) number, missing or invalid patient date of birth, invalid National Drug Code (NDC), and missing patient first or last name. Reporting of erroneous data to the PMP violates Minnesota Statutes §152.126. In addition, such errors may indicate violations of other federal and state statutes and rules. For example, submission of an obviously "phony" DEA registration number may indicate that the pharmacy filled a CS prescription that did not contain the prescriber's DEA registration number as required by both the federal and Minnesota CS acts. An invalid NDC may mean that the pharmacy dispensed an incorrectly labeled (ie, misbranded) drug.

Pharmacies/uploaders are **required** to correct and resubmit the data within seven days of the initial notification via the edit/error report. Beginning October 1, 2015, PMP staff began more closely auditing for errors and corrections, and communicating to pharmacists-in-charge (PICs) and/or data uploaders when necessary.

The Minnesota PMP staff encourages data uploaders, as well as PICs, to contact the vendor-supported technical help desk regarding uploading of data, data corrections, and data resubmission. The technical help desk is currently supported by Health Information Designs, LLC, at mnpdm-info@hidinc.com or 866/792-3149.

When a pharmacy notices and corrects an error **after** data is uploaded to the PMP database, corrected data may not automatically be sent to the PMP. The data uploader must resubmit the prescription data and ensure that the original record containing the error is removed. Failure to remove the record containing errors results in duplicate records in a patient's PMP report.

The Board encourages all pharmacy personnel, especially PICs and data uploaders, to have open communications regarding prescription errors and daily uploads. Thank you to those pharmacies/data uploaders who uphold data integrity and upload complete, accurate data to the PMP database daily. For further information on data uploading, please visit the PMP website at *www.pmp.pharmacy.state.mn.us* and go to the "PMP Data Uploaders" section. If you still have questions, the PMP staff can also be reached at minnesota.pmp@state.mn.us or 651/201-2836.

Pharmacy Technicians and CE

All pharmacy technicians should have certified **to the Board** the completion of their continuing education (CE) for the two-year technician CE period that ended on July 31, 2015. Many technicians still appear to be confusing the Board's requirement to complete 20 hours of CE every two years with the CE requirements necessary to become nationally certified technicians.

On August 17, 2015, the Board changed the registration status of all technicians who had **not** certified the completion of their CE for the period ending July 31, 2015. The status was changed from "Active" to "Owes CE." Many technicians are now in that status.

Each PIC should verify the registration status of all technicians working in his or her pharmacy. This can be done by visiting the Board's website at *www.pharmacy.mn.gov,* clicking on the "License Verification" button, and typing in the registration number or name of the technician. Please look under "License Status" and make sure that the status is "Active."

If the status of a technician is **not** "Active" or "Owes CE," have the technician call the Board office. If the status is "Active," the PIC needs to do nothing else. If the status is "Owes CE," the PIC should ask the technician to submit copies of proof of CE participation to the Board. When submitting proof of CE participation, technicians should include their name and registration number. Once proof of CE participation is received and approved, technician registration status will be changed back to "Active," and a renewal application will be appended to the technician's record.

continued on page 5

continued from page 4

If technicians do not submit proof of CE participation, or if the CE is not approved, they will not have a renewal application appended to their record and will not be able to renew their registration. In that case, as of January 1, 2016, those individuals will not be allowed to work as pharmacy technicians. If these technicians do work on or after January 1, 2016, both the technicians and their PICs could be subject to disciplinary action.

Technician Training

Rules that the Board adopted in 2011 regarding registration requirements for technicians have been in full effect since January 1, 2014. One portion of that rule change requires newly registered technicians to complete training within 12 months of their initial registration. (Technicians registered prior to January 1, 2013 – who have not let their registration lapse for longer than 12 months – were "grandfathered" in and do not have to complete training.) This training can be completed through a Board-approved, accredited vocational/technical institution or college; a pharmacy technician training program accredited by a Board-approved, national organization that accredits pharmacy technician training programs; or a pharmacy technician training program provided by a branch of the US Armed Forces or US Public Health Service.

Another option for training is an employer-based training program. The rule language concerning employer-based training is as follows (emphasis added).

> [A]n employer-based pharmacy technician training program that includes a minimum total of 240 hours on a one-year period to include both theoretical and practical instruction. **An employer utilizing such a program must develop and regularly update a technician training manual** that must be available for board inspection upon request. **The employer must also supply a technician who completes the training program with written evidence of completion.** The employer-based pharmacy technician training program must include written guidelines, policies, and procedures that define the specific tasks the technician will be expected to perform.

Please note that it is no longer acceptable for an employer to rely on any sort of informal on-the-job technician training. Any technician who was first registered on or after July 1, 2013, **must** complete appropriate training within 12 months of his or her initial registration. If an employer chooses to rely on an internal training program, the employer **must** develop a comprehensive technician training manual. The training manual must meet the requirements listed in the Board's Pharmacy Technician Training Guidance, which can be found on the Board's website.

Employers must also provide a document to technicians that indicates that they have completed employer-based training. This could be a letter or certificate, as long as it indicates that training was completed and the date on which the training was completed. The Board is starting to get complaints from technicians and pharmacies alleging that a previous employer has either not ensured that a technician has completed training or has not provided a technician with proof of completion of training. The Board can take disciplinary action against the license of the pharmacy if such complaints are substantiated.

The *Minnesota Board of Pharmacy News* is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

Cody Wiberg, PharmD, MS - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager