January 2019

Minnesota Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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www.pharmacy.mn.gov

Disciplinary Actions

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

Board Officers for 2019

At its November 28, 2018 meeting, the Board elected Dr Stacey Jassey to be its president for 2019. Governor Mark Dayton appointed Dr Jassey to her current term in January 2018, but she has served on the Board before. On March 17, 2008, then-Governor Tim Pawlenty appointed her to a four-year term to fill the position that was vacated by Betty Johnson. Dr Jassey served most of the term but had to resign from the Board in 2011 when a new employer asked her to do so as a condition of taking the position it had offered her. Dr Jassey has over 25 years of experience in the pharmacy profession. She currently works as a pharmacist for Genoa, a company with pharmacies that specialize in meeting the prescription needs of mentally ill patients. Her past experience includes a position as a community clinical pharmacist for Walgreens, where she also served as one of the nationwide interpreters for Spanish-speaking Walgreens patients. She also worked as a pharmacist for Target (before the CVS buyout). Dr Jassey has also held positions with pharmaceutical manufacturers. She is an assistant professor at the University of Minnesota College of Pharmacy, from which she received her bachelor of science and doctor of pharmacy degrees.

At the same meeting, the Board elected Dr Mary Voelker Phipps to be vice president for 2019. Dr Phipps, of St Cloud, MN, was appointed to the Board by Governor Dayton in 2016. She is the system director of pharmacy for CentraCare Health. She oversees pharmacy services at St Cloud Hospital, in five critical access hospitals across central Minnesota, an infusion pharmacy, and four clinic-based community/outpatient pharmacies. Prior to coming to CentraCare Health 17 years ago, she worked in various positions at Mercy Hospital Medical Center and Drake University in Des Moines, IA. Dr Phipps earned her bachelor of science degree in pharmacy at the University of Minnesota and her doctor of pharmacy degree at the University of Kentucky.

The Board also re-elected Dr Cody Wiberg to be secretary for 2019. The Board's secretary is a non-voting officer of the Board who is also designated executive director and chief administrative officer. Dr Wiberg received his doctor of pharmacy degree from the University of Minnesota in 1985. He has worked as a clinical pharmacist, hospital pharmacist, community pharmacist, and nursing home consultant. From 1999 until he joined the Board in September 2005, he was the pharmacy program manager for the Minnesota Department of Human Services. Dr Wiberg is a clinical assistant professor for the University of Minnesota College of Pharmacy. He is also an instructor and course director for the University of Florida Graduate School, from which he received his master of science degree in pharmacy policy and outcomes in 2009, and a course director for the University of Wyoming Graduate School. Dr Wiberg made the *Minnesota Physician* quadrennial list of the state's "100 Influential Minnesota Health Care Leaders" in 2008, 2012, and 2016. He also received the 2017 Century Mortar Club's Friend of the College Award from the University of Minnesota College of Pharmacy.

Pharmacist License Renewals

There are approximately 9,000 individuals who currently hold an active pharmacist license issued by the Board. Pharmacists who want to renew their license for the license period that starts on March 1, 2019, may do so at this time. The Board encourages licensees to take advantage of the online renewal option for faster processing.

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National Pharmacy Compliance News

January 2019

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.*

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy,* the guidelines are available at *www.ajhp.org/content/75/19/1493.* ASHP's October 2, 2018 press release can be found in the News section at *www.ashp.org.*

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.* In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.*

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.* This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.*

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *https://againstopioidabuse.org.*

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- generic substitution is recommended as part of the pharmacist's dispensing role;
- pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at *www.fip.org* in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes,* will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit *http://fdapasediabetes.e-paga.com.*

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at *www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.*

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To renew your license, visit the Board's website and select the "Online Services" menu item. This will take you to the Board's sign-in page. Click on the appropriate links and follow the prompts. The renewal screen will also allow you to change your address, update your employment, or change your license status. If you have any questions, you may call the Board during normal business hours at 651/201-2825, and one of its staff members will assist you.

If you would rather submit a paper renewal, follow the directions in the paragraph above. Use the appropriate links on your account page to make any address and employment changes. Once you have made any necessary changes to your addresses and employment, instead of clicking on "Renewal-In-Progress," click on "Print Pharmacist Renewal Invoice" at the bottom of the page. Print the invoice, sign and date it, and send it to the Board office with your payment. If you do not have internet access, contact the Board office and the Board will print a renewal and mail it to you.

The renewal period for pharmacists opened in mid-December, and the deadline for completing the renewal process is **February 1,** not February 28, as many people mistakenly believe. The month of February is actually a grace period during which no late fees are assessed for pharmacists who have missed the February 1 deadline. If your completed application and required fee are not received by the Board office prior to March 1, your licensure will expire and the late fee will be imposed. You will not be allowed to practice pharmacy in the state of Minnesota until the Board receives the completed application and fees.

Pharmacy Technicians

Registration

Pharmacy technician registration renewals were due on December 1, 2018. Technicians were then given the month of December as a grace period. The registrations of technicians who failed to renew by December 31, 2018, have expired. Individuals cannot continue working as technicians if their registrations have expired. Pharmacists-in-charge (PICs) are encouraged to verify that technicians working under their supervision have current registrations. That can be done by using the license verification feature on the Board's website. If an unregistered individual performs duties that require a technician registration, the Board can take disciplinary action against that individual, the PIC, and the pharmacy.

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. The 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 United States Armed Forces or Public Health Service.

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

> (4) an 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 some 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 Document 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 a 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.

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Continuing Education

Minnesota-registered pharmacy technicians are reminded that continuing education (CE) reporting is due no later than July 31 of every odd-numbered year. There are now approximately six months left during which technicians can complete and report their CE for the period of August 1, 2017, to July 31, 2019. Upon completion of at least the required 20 hours of CE, technicians can visit the Board's website, choose the "Online Services" menu item, log in to the Board's system, and certify the completion of their CE. Alternatively, technicians can access a certification of completion of CE form on the Board's website, fill out and sign the form, and send it to the Board office. Note that technicians who first received their registration from the Board after August 1, 2017, may need to complete less than 20 hours of CE. Those individuals need to complete an amount of CE that is pro-rated based on the number of months that they had an active registration during the CE cycle. Those technicians can determine the number of hours that they need to complete by logging in to their accounts in the "Online Services" section of the Board website.

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.

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