February 2018

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

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.

Criminal Background Checks

Minnesota statutes require all individuals seeking to be licensed as a pharmacist for **initial** licensure, licensure **by transfer** (reciprocity), or license **reinstatement** to complete a fingerprint-based criminal background check (CBC) (Minnesota Statute §214.075). This requirement went into effect on January 1, 2018. At this time, pharmacists with existing licenses do **not** have to complete a CBC. However, it is possible that the Minnesota Legislature will amend the statutes to require licensees to have a one-time CBC in the future, in conjunction with license renewal. Because pharmacist-interns and pharmacy technicians are registered, not licensed, they will not have to undergo a CBC.

Note that the requirement to have a CBC applies to all professionals licensed by Minnesota's Health Licensing Boards (HLBs). The HLBs have cooperatively established the Criminal Background Check Program to help applicants efficiently complete this mandatory background check.

When an individual applies for the types of licensure mentioned above, the CBC fee must be bundled with other licensing fees and paid at the same time. After applicants have paid all required licensing fees and the CBC fee, they will be provided with a packet from the CBC Program, which contains additional information and directions. Applicants are responsible for having their fingerprints taken promptly and for completing all required paperwork so as not to delay finalizing their license application. Previously taken fingerprints cannot be used. Applicants can have fingerprints taken at certain specified locations. However, some external agencies (eg, law enforcement agencies) charge a fee for fingerprinting services. Fingerprinting can be done without a fee at the CBC Program office at the address listed at the end of this article. Applicants should contact that office to make an appointment after they receive the information packet.

The time required for a CBC varies with the workload at the Minnesota Bureau of Criminal Apprehension (BCA). Fingerprints are crosschecked with the databases of the BCA and the Federal Bureau of Investigation (FBI). During periods of high numbers of CBC requests, BCA's records search may take weeks. For fastest service, applicants may come to the Board of Pharmacy office with their license application and a check for all fees and obtain the CBC information packet. All of the CBC forms may be filled out on site, and with a prearranged appointment, fingerprinting may be done the same day at the CBC Program office. Please note that the report received from the BCA and FBI is only valid for a year. Applications that are not completed within a year of the CBC will be invalid and no fees will be refunded.

Please direct any questions you have about the background check process to CBC Program staff, not to the Board. The contact information for CBC Program staff is:

Criminal Background Check Program
2829 University Ave SE, Ste 555
Minneapolis, MN 55414-4202
Telephone: 651/201-2822
Email: cbc.staff@state.mn.us

Prescription Monitoring Program – Required Registration

The Minnesota Prescription Monitoring Program (PMP) is a tool that may be used by prescribers and pharmacists to assist in managing their patients' care. It contains information provided by Minnesota-licensed pharmacies and prescriber dispensers. Pharmacies and prescribers who dispense from their office submit prescription data to the PMP system for all Schedule II, III, IV, and V controlled substances (CS), butalbital, and gabapentin that are dispensed within or into Minnesota. Minnesota-licensed prescribers and pharmacists, and their delegated staff, may be authorized to access information from the PMP database. The program was implemented to promote public health and welfare by providing a tool for the

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NABPF
National Association of Boards of Pharmacy Foundation

FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

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detection of diversion, abuse, and misuse of CS, butalbital, and gabapentin.

State law requires all Minnesota-licensed pharmacists practicing within the state to register for and maintain a user account with the PMP. That requirement went into effect on July 1, 2017. Pharmacists who are licensed by the Board and who practice pharmacy within the state should register for an account at this time if they have not already done so. Pharmacists whose licenses are in "Emeritus" or "Inactive" status do not need to register for a PMP account. The following actively licensed pharmacists do **not** need to register for a PMP account: pharmacists who have completely retired and never practice pharmacy; and pharmacists who work in positions that do not require licensure as a pharmacist (for example, a pharmacist who is also an attorney and who never practices pharmacy). Pharmacists may contact the Board office by calling 651/201-2825 or sending an email to pharmacy.board@state.mn.us if they have a question about their need to register for a PMP account.

Pharmacy Technician Registration

Pharmacy technician registration renewals were due on December 1, 2017. Technicians were then given the month of December as a "grace period." The registrations of technicians who failed to renew by December 31, 2017, 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.

Pharmacist License Renewals

Pharmacists who want to renew their license for the license period that starts on March 1, 2018, may do so at this time. To renew online, please visit the Board's website at *www.pharmacy.mn.gov* and select "Online Services" from the Quick Links tab in the upper right-hand corner of the page. If you have already created a login, click on "Login" and enter your username (email address) and password. Then, follow the steps in the paragraph below. If you have not created a login, click on the "Create New Login" button on the left. Fill in your Social Security number (ie, XXX-XX-XXXX), birth date (ie, 01/01/1955), and license number (ie, 1XXXXX). Then, follow the steps in the paragraph below.

Click on "Renewal In Progress" on the right side of the page. You will come to the change address page. Please follow the instructions provided during the renewal process. If you have any questions, you may call the Board during normal business hours for assistance at 651/201-2825 and press 0.

If you have an internet connection but are not willing to make a payment online, follow the directions in the first paragraph in this article. Use the appropriate links on your account page to make all address and employment changes prior to the next step. You are only able to change employment if you work at a Minnesota-licensed facility and have the license number. If you work somewhere else or cannot enter your new employment, please complete the change of employment form on the Board's website and email the form to pharmacy.board@state.mn.us; or, print and fax the form to 612/617-2262 and Board staff will update it for you.

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 an internet connection, contact the Board office and Board staff will print a renewal and mail it to you.

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.

Pharmacist Continuing Education

Minnesota-licensed pharmacists are reminded that continuing education (CE) reporting is due no later than October 1 of every even-numbered year. There are now approximately eight months left during which pharmacists may complete and report their CE for the period from October 1, 2016, to September 30, 2018. Upon completion of at least the required 30 hours of CE, pharmacists may visit the Board's website *(www.pharmacy.mn.gov),* choose "Online Services" from the Quick Links menu, log into the Board's system, and certify the completion of their CE. Alternatively, pharmacists may 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's office. (Note that pharmacists first licensed after October 1, 2016, have a pro-rated number of CE hours that they must complete. You can determine the number of CE hours that you need to complete by logging into your Board online account.)

Minnesota Pharmacy Syringe Access Initiative

Minn. Stat. §151.40, Subdivision 2, which became effective in 1998, provides for pharmacy sales of needles/syringes in quantities of 10 or fewer without a prescription, following provisions described below. The legislation also charged the Minnesota Department of Health (MDH) with developing a statewide disposal plan. The goal of this legislation is to reduce transmission of human immunodeficiency virus (HIV) and hepatitis C (HCV) infections among injection drug users (IDUs). Provisions are as follows:

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- Syringes cannot be openly displayed for purchase by customers;
- Pharmacies may not advertise the availability of syringes;
- Pharmacies are encouraged to supply information on HIV and/or HCV testing and prevention, including referral to websites; and
- An individual may legally possess up to 10 unused syringes at a time.

Many pharmacies have been participating with the Syringe Access Initiative for more than 20 years, resulting in successfully reducing the transmission of HIV and HCV among IDUs in Minnesota. The initiative also provides IDUs with information on HIV and HCV prevention, health care resources, drug treatment access, and the safe disposal of used syringes. The following are some key highlights:

- The Board, the Minnesota Pharmacists Association, and the Minnesota Society of Health-System Pharmacists issued resolution statements in 1998 supporting this HIV/HCV prevention legislation. The Board still supports this initiative and encourages pharmacies to participate.
- Nationally, the American Medical Association, the American Pharmaceutical Association, the Association of State and Territorial Health Officials, and the National Alliance of State and Territorial AIDS Directors have adopted policies related to nonprescription pharmacy sale of syringes.
- Community outreach programs and the Minnesota AIDS Project AIDSLine are referring IDUs to participating pharmacies. Through the ongoing collaboration with the Minnesota Pollution Control Agency, the Minnesota chapter of the American Diabetes Association, community-based organizations, and Minnesota pharmacies, statewide disposal continues to improve.
- A comprehensive disposal brochure, "Safe Disposal Options for Needles and Syringes," is available from the Minnesota Pollution Control Agency.

To determine if your pharmacy is already a participant, please visit this MDH web page. If your pharmacy is not listed and you want to participate, please complete the Pharmacy Registration: Syringe Access Initiative online form. This will allow your pharmacy staff to sell 10 or fewer syringes without a prescription and contribute to maintaining Minnesota's success in preventing the transmission of HIV and HCV.

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
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