July 2020

Minnesota Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Disciplinary Actions

Because of space limitations, information on disciplinary actions is no longer 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.

COVID-19

In response to the coronavirus disease 2019 (COVID-19) pandemic, the Board has issued an extensive COVID-19 FAQ document, available on its website.

The FAQ document contains information from a variety of sources that should be useful to licensees and registrants. It also describes how the Board will be effectively granting blanket variances to certain rules and exercising enforcement discretion for certain sections of Minnesota Statutes. Licensees and registrants are encouraged to check the document regularly for updates.

2020 Legislation

During the 2020 regular session, the Minnesota Legislature enacted several provisions that will have an impact on the Board's licensees and registrants. This edition of the *Newsletter* includes a brief description of some of the major changes. For detailed information, please see the 2020 Minnesota Legislation Affecting Pharmacy document available on the Board's website.

Minnesota Insulin Safety Net Program

The Legislature passed the Alec Smith Insulin Affordability Act, which Governor Tim Walz signed into law on April 15, 2020 (codified primarily as Minnesota Statute §151.74). The act creates a Minnesota Insulin Safety Net Program (MnISNP) that will aid individuals who cannot afford insulin. One part of the program allows eligible individuals who are in urgent need of insulin to receive a one time, 30-day supply of insulin from their pharmacy for a $35 co-pay. An emergency supply can normally be obtained only once in a 12-month period. However, there is an option for some individuals to receive a second 30-day supply in certain circumstances. The insulin manufacturer will reimburse the pharmacy for the insulin or send the pharmacy a replacement supply.

The second part of the program requires manufacturers to provide insulin to eligible individuals for up to one year, with the option to renew annually. The manufacturers will have to provide up to a 90-day supply of insulin for a co-pay of no more than $50. Individuals with insurance may also obtain insulin through a manufacturer's co-pay program, which waives all or part of the co-pay that the patient normally must pay.

Language was adopted that clarifies that tribal identification cards as defined in section 171.072, paragraph (b) can be used to establish the Minnesota residency of individuals applying for the MnISNP.

Pursuant to Minnesota Statutes §214.108, the Board is allowed to offer guidance to licensees about the application of the statutes and rules that the Board enforces. The Board issued a guidance concerning the MnISNP at its May 20, 2020 meeting, which is available on the Board's website. The guidance also has information for patients, pharmacists, and manufacturers, along with other links and resources.

Independent Prescribing by Pharmacists of Self-Administered Hormonal Contraceptives, Nicotine Replacement Medications, and Opiate Antagonists

Pharmacists will be able to independently prescribe self-administered contraceptives, nicotine replacement medications, and opiate antagonists, provided that:

- They follow a protocol developed by the Board in consultation with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; professional pharmacy

continued on page 4

National Pharmacy Compliance News

July 2020

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.

FDA Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy® (NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at *https://www.fda.gov/media/137125/download.*

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law.* "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA's website by visiting *www.fda.gov/media/136841/download.*

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

"This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at *https://www.cdc.gov/media/phishing.html.*

continued from page 1

associations; professional associations of physicians, physician assistants, and advanced practice registered nurses.

- ♦ They complete appropriate training programs and continuing education.
- ♦ They provide appropriate counseling to patients.

The Board will provide additional information to pharmacists once the protocols have been developed. The Board has until January 1, 2021, to develop the protocols but will try to develop them by August 1, 2020, which is the effective date of the legislation.

COVID-19 Vaccines

Pharmacists were authorized to administer a Food and Drug Administration (FDA)-approved COVID-19 vaccine for patients six years of age and older.

The Board's Recommendations Concerning the Scheduling of Controlled Substances Were Enacted

Fentanyl analogs, synthetic cannabinoids, tianeptine, and benzodiazepines (that have not been approved by FDA) were added to Schedule I. A dronabinol product (Syndros®) was added to Schedule II. A veterinary product containing chorionic gonadotropin was exempted from the schedules.

Therapeutic Interchange During a Declared COVID-19 Peacetime Emergency

Pharmacists will be able to engage in therapeutic interchange during a declared COVID-19 peacetime emergency (and for 60 days after it ends) if:

1. the drug prescribed is in short supply and the pharmacist is unable to obtain it from the manufacturer, drug wholesalers, or other local pharmacies;
2. the pharmacist is unable to contact the prescriber within a reasonable period of time to get authorization to dispense a drug that is available;
3. the pharmacist determines a therapeutically equivalent drug to the one prescribed is available and is in the same American Hospital Formulary Service pharmacologic-therapeutic classification;
4. the pharmacist informs the patient as required in Minnesota Statutes, section 151.21, subdivision 7a, paragraph (b), and provides counseling to the patient, as required by the Board rules, about the substituted drug; and
5. the pharmacist informs the prescriber as soon as possible that the therapeutic interchange has been made.

Issuance of Prescriptions for Substance Use Disorders During a Declared COVID-19 Peacetime Emergency

During a declared COVID-19 peacetime emergency (and for 60 days after it ends), for purposes of Minnesota Statutes, section 151.37, subdivision 2, paragraph (d), the requirement for an examination of a patient shall be met if the prescribing practitioner has performed a telemedicine examination of the patient before issuing a prescription drug order for the treatment of a substance use disorder.

Language Clarifying That Physician Assistants Can Prescribe Controlled Substances

Added to Minnesota Statutes §152.12.

Opiate Manufacturer Licensing Fee and Opiate Fund Clarifications

Language clarifying that opiate manufactures must pay a licensing fee of $55,260 (rather than $55,000) was adopted. Clarifications concerning the opiate fund into which certain revenues that the Board collects were also adopted.

Clarifying Language Related to Medical Gas Dispensers

Language was adopted that changed references of "medical gas distributors" to "medical gas dispensers." The entities that the Board has been registering as medical gas distributors are actually only allowed to dispense medical gases to patients, pursuant to a prescription. Facilities that sell medical gases at wholesale are licensed as medical gas wholesalers.

Change in Language Required to Be on Generic Substitution Signs in Pharmacies

Minnesota Statutes 2018, section 151.21, subdivision 4a, was amended to read:

> Subd. 4a. Sign. A pharmacy must post a sign in a conspicuous location and in a typeface easily seen at the counter where prescriptions are dispensed stating: "In order to save you money, this pharmacy will substitute whenever possible an FDA-approved, less expensive, generic drug product, which is therapeutically equivalent to and safely interchangeable with the one prescribed by your doctor **or advanced practice registered nurse,** unless you object to this substitution."

This means that pharmacies will have to replace or modify their existing generic substitution signs by August 1, 2020.

Governor Walz Makes Appointments

Governor Walz reappointed **Mary Phipps, PharmD, RPh,** of St Cloud, MN, to a four-year term on the Board. She earned her bachelor of science degree in pharmacy at the University of Minnesota and doctor of pharmacy degree at the University of Kentucky.

Dr Phipps is the system director of pharmacy for CentraCare Health. She oversees pharmacy services at St Cloud Hospital and in five critical access hospitals across central Minnesota, as well as an infusion pharmacy and four clinic-based retail pharmacies. Prior to coming to CentraCare, she worked in various positions at Mercy Hospital Medical Center and Drake University in Des Moines, IA.

Governor Walz also appointed **Kendra Metz, PharmD, RPh,** of Moose Lake, MN, to a four-year term on the Board. Dr Metz graduated in 2012 from the University of Minnesota, Duluth campus. She has since then been the pharmacist-in-charge for Thrifty White, a high-volume pharmacy in Moose Lake. With a passion for providing health services in rural areas, she expanded immunizations and medication therapy management, and developed a collaborative practice agreement at her practice site. Dr Metz also encourages rural health to pharmacy students as a preceptor, displaying a high level of care for patients, fellow health care providers, and long-term care facilities in her rural community. She values education and safety, which is evident in the numerous medication training presentations, opioid and naloxone projects, and other collaboration projects she has been involved in with local entities, Carlton County Public Health, Minnesota Department of Health, and the University of Minnesota.

Staff Changes

Pharmacy Surveyor Steven Huff, RPh, recently retired, after ably serving the Board and the public for over eight years. Mr Huff graduated in 1980 with a bachelor of science degree in pharmacy from the University of Minnesota. He had previous experience in community pharmacy, hospital pharmacy, long-term care pharmacy, and pharmaceutical manufacturing and wholesaling. While working for the Board, he earned certificates from the CriticalPoint Sterile Compounding Boot Camp; National Certified Investigator and Inspector Training (through the Council on Licensure, Enforcement and Regulation); and Investigator Training (through the National Association of Drug Diversion Investigators). Additionally, he represented the Board on the Minnesota Department of Health's Minnesota Medical Cannabis Selection Committee. He would like to salute all the "amazing pharmacists out there serving the state of Minnesota." The Board and its staff wish Mr Huff a long and enjoyable retirement. (Note that due to a state hiring freeze, his position will not be filled for the foreseeable future.)

The Board was given an increased appropriation during the 2019 legislative session to create a new pharmacy surveyor position, which was filled (before the hiring freeze) by Kelly Hadsall, PharmD, RPh. Dr Hadsall graduated in 1996 from the University of Minnesota with a bachelor of science in biology (magna cum laude). In 2001, she graduated with a doctor of pharmacy degree (magna cum laude) from the University of Minnesota. Dr Hadsall was a research fellow in cardiology at the University of Minnesota after graduating from the college of pharmacy. She has many years of experience working in hospital pharmacy settings.

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