April 2020

Minnesota Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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https://mn.gov/boards/pharmacy

Editor's Note: *The content of the Minnesota Board of Pharmacy's Newsletter was finalized prior to the coronavirus disease 2019 (COVID-19) outbreak. Licensees should check the Board's website for the most up-to-date information.*

Disciplinary Actions

Because of space limitations, information on disciplinary actions is no longer included in the *Board's 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.

Pharmacist License Renewals

By this time, all pharmacists who wanted to renew their licenses for the period starting March 1, 2020, should have done so. Pharmacists who did not renew their licenses by that date should not be practicing pharmacy in Minnesota. Practicing pharmacy without a license is grounds for disciplinary action and can result in the pharmacist having to pay a civil penalty. Pharmacists who have not renewed their licenses should contact the Board's office as soon as possible for instructions on how to renew.

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 six months left, during which pharmacists can complete and report their CE for the period from October 1, 2018, to September 30, 2020. Upon completion of at least the required 30 hours of CE, pharmacists can visit the Board's website, choose "How do I" on the top right above the navigation bar, then select "Login to My Account," log in to the system, and certify the completion of their CE. Alternatively, pharmacists can access a Certification of Completion of CE form on the Board's website by selecting "Forms" from the top navigation. Fill out and sign the form and send it to the Board's office.

DEA Registration Numbers and National Provider Identifiers

Various practitioners continue to notify the Board office about pharmacies calling to request a Drug Enforcement Administration (DEA) registration number even when the prescription in question is not for a controlled substance (CS). In addition, veterinarians have called with concerns that pharmacies are indicating that they cannot fill prescriptions without having the veterinarian's National Provider Identifier (NPI). Minnesota Statute §152.11, subd. 2a states that:

> A prescription need not bear a federal drug enforcement administration registration number that authorizes the prescriber to prescribe controlled substances if the drug prescribed is not a [CS] in Schedule II, III, IV, or V. No person shall impose a requirement inconsistent with this subdivision.

Therefore, pharmacists and pharmacies should not be requesting DEA registration numbers for non-CS prescriptions.

The Centers for Medicare & Medicaid Services addressed the issue of veterinarians and NPIs several years ago by stating that veterinarians are not eligible for NPIs because they do not meet the regulatory definition of "health care provider" as defined per 45 Code of Federal Regulations 160.103. Please be advised that just because the Healthcare Provider Taxonomy Code Set has a code for "veterinarian" does not mean a veterinarian is a health care provider and, thus, eligible for an NPI. Any entity that insists veterinarians obtain an NPI are attempting to require veterinarians to obtain NPIs fraudulently (ie, because the NPI Application/Update Form and its internet equivalent require that the NPI applicant indicate that he/she/it meets the regulatory definition of health care provider and a veterinarian does not).**Therefore, pharmacists and pharmacies should not ask veterinarians to provide an NPI.**

National Pharmacy Compliance News

April 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.

President Trump Signs Legislation Extending Schedule I Status for Fentanyl Analogues

A law to extend the Schedule I status of fentanyl analogues for another 15 months was signed into law by President Donald J. Trump on February 6, 2020. Synthetic fentanyl analogues, often illegally manufactured, are widely believed to be fueling the "third wave" of the opioid crisis, as detailed in the October 2019 issue of *Innovations*® (pages 8-11), which can be accessed through the Publications section of the National Association of Boards of Pharmacy®'s website.

In February 2018, Drug Enforcement Administration (DEA) issued a temporary order to establish fentanyl-related substances as Schedule I. The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act extends the DEA order, which was set to expire on February 6, 2020. The bill requires the Government Accountability Office to produce a report within 12 months on the public health and safety effects of controlling fentanyl-related substances, according to *Homeland Preparedness News*.

Drug Overdose Deaths Related to Prescription Opioids Declined by 13% in 2018

Fatalities related to the use of prescription opioids declined by 13% in the United States during 2018, according to the 2019 National Drug Threat Assessment released by DEA. Despite this encouraging news, the report makes it clear that the opioid crisis continues at epidemic levels. Specifically, controlled prescription drugs remain a major factor in the record number of overdose deaths since 2017. Benzodiazepines and antidepressants were involved in an increasing number of overdose deaths.

Fentanyl and similar synthetic opioids also remain a major point of concern. Fentanyl maintained high availability through most of the US in 2018. Illegally manufactured versions of the powerful opioid continue to be smuggled into the US, primarily in the form of counterfeit pills made to look like prescription opioids and powder. Fentanyl remains the "primary driver" of the current opioid crisis, according to the report.

"Illicit drugs, and the criminal organizations that traffic them, continue to represent significant threats to public health, law enforcement, and national security in the United States," a DEA press release states. "As the National Drug Threat Assessment describes, the opioid threat continues at epidemic levels, affecting large portions of the United States."

Drug-Resistant Infections Are Increasing

A new report on antibiotic infections released by the Centers for Disease Control and Prevention (CDC) estimates more than 2.8 million antibiotic-resistant infections occur each year, and more than 35,000 Americans are dying annually as a result. While the report notes that prevention and infection control efforts in the US are working to reduce the number of infections and deaths caused by antibiotic-resistant germs, the number of people facing antibiotic resistance is still too high. "More action is needed to fully protect people," the report states.

The report lists 18 antibiotic-resistant bacteria and fungi and places them into three categories (urgent, serious, and concerning) based on clinical impact, economic impact, incidence, 10-year projection of incidence, transmissibility, availability of effective antibiotics, and barriers to prevention. It also highlights estimated infections and deaths since the last CDC report in 2013, aggressive actions taken, and gaps that are slowing progress.

The full report is available on the CDC website.

NASEM Report Recommends Framework for Opioid Prescribing Guidelines for Acute Pain

Contracted by Food and Drug Administration (FDA), a December 2019 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) seeks to develop evidence-based clinical practice guidelines for prescribing opioids for acute pain. The report, *Framing Opioid Prescribing Guidelines for Acute Pain:*

Developing the Evidence, also develops a framework to evaluate existing guidelines, and recommends indications for which new evidence-based guidelines should be recommended.

As part of its work, NASEM examined existing opioid analgesic prescribing guidelines, identified where there were gaps in evidence, and outlined the type of research that will be needed to fill these gaps. NASEM also held a series of meetings and public workshops to engage a broad range of stakeholders who contributed expert knowledge on existing guidelines, and provided emerging evidence or identified specific policy issues related to the development and availability of opioid analgesic prescribing guidelines based on their specialties.

"We recognize the critical role that health care providers play in addressing the opioid crisis – both in reducing the rate of new addiction by decreasing unnecessary or inappropriate exposure to opioid analgesics, while still providing appropriate pain treatment to patients who have medical needs for these medicines," said Janet Woodcock, MD, director of FDA's Center for Drug Evaluation and Research in a statement. "However, there are still too many prescriptions written for opioid analgesics for durations of use longer than are appropriate for the medical need being addressed. The FDA's efforts to address the opioid crisis must focus on encouraging 'right size' prescribing of opioid pain medication as well as reducing the number of people unnecessarily exposed to opioids, while ensuring appropriate access to address the medical needs of patients experiencing pain severe enough to warrant treatment with opioids."

FDA will next consider the recommendations included in the report as part of the agency's efforts to implement the SUPPORT Act provision requiring the development of evidence-based opioid analgesic prescribing guidelines.

The report can be downloaded for free on the NASEM website.

New Research Shows Pharmacists Positively Impact Hospital Care Transitions

Patients who received focused attention from pharmacists during hospital stays expressed higher satisfaction, according to research presented at the American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition. The study centered on the effect of pharmacists educating patients about medications as they transitioned out of hospital care. During the study, pharmacists reconciled patients' medications before discharge, talked with patients about the medications they were taking, and contacted them by phone after discharge to discuss their care.

Of the 1,728 patients included in the study, 414 received the full transition-of-care education protocol, including a follow-up pharmacist phone call. Those patients showed a 14.7% increase in the overall average mean score, as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems survey, which assesses patients' perceptions of their care after discharge. A post hoc analysis also showed that 30-day readmission rates dropped from 17.3% to 12.4% when a post-discharge phone call was made to patients as a part of the study.

"Pharmacists play a multitude of vital roles for patients during a hospital stay, including comprehensive medication management and ensuring medication safety. Now, they can feel increasingly confident about their role in helping patients when transitioning from different levels of care. Our findings add to growing literature demonstrating that pharmacist involvement in hospital discharge improves outcomes and safety," said Katherine L. March, PharmD, BCPS, clinical pharmacy specialist at Methodist University Hospital in Memphis, TN, in a press release.

Kickbacks and Fee Splitting

Generally, it is unprofessional conduct for a pharmacist or pharmacy to enter into any arrangement whereby a pharmacy, in which the prescribing practitioner does not have a significant ownership interest, fills a prescription drug order and the prescribing practitioner is involved in any manner, directly or indirectly, in setting the price for the filled prescription that is charged to the patient, the patient's insurer or pharmacy benefits manager, or other person paying for the prescription. For example, a pharmacy should not enter into an arrangement through which:

- it receives a prescription from a prescriber;
- it fills the prescription;
- it bills the prescriber, rather than the patient; and
- the prescriber then bills the patient for a higher cost than the prescriber paid the pharmacy.

This is just one example; there are other possible arrangements that would also not be allowed. However, a veterinarian and a pharmacy may enter into such an arrangement provided that the client or other person paying for the prescription is notified, **in writing and with each prescription dispensed,** about the arrangement, unless such arrangement involves pharmacy services provided for livestock, poultry, and agricultural production systems, in which case client notification would not be required. Any pharmacy licensed by the Board that has entered into any such arrangement with veterinarians who treat animals other than food-producing animals, must provide written notification about the arrangement with each prescription filled.The pharmacy is not required to provide specific information about the financial details of the arrangement. However, the notification must explain that there is a financial relationship between the pharmacy and the veterinarian. A notification on the website of a pharmacy or a sign posted within the pharmacy is not enough. Nothing in the statutes prevents the client from asking about the arrangement and the amount of money received by both the pharmacy and the veterinarian.

Health Professionals Services Program

The Board investigates at least a dozen complaints each year against pharmacists, interns, and technicians involved in the alleged diversion of CS, the abuse of alcohol, or the inability to safely practice due to a mental illness. The Board takes such complaints seriously because, left untreated, substance abuse and other mental illnesses can put patients at risk. Of course, the health of the pharmacist or technician is also at risk. Fortunately, licensed and registered health professionals can get help before they become the subject of disciplinary action. Created in 1994 as an alternative to Board discipline, the state of Minnesota's Health Professionals Services Program (HPSP) offers a proactive way to get confidential help for illnesses.

HPSP evaluates professionals and, if necessary, enters into participation agreements with them. Participation agreements include monitoring conditions. HPSP monitors treatment progress, work quality, and medication use. For persons with substance use disorders, HPSP requires mutual support group attendance and random urine drug screens. Other monitoring requirements may include counseling, work limitations, and other conditions that address both the professional's illness and public safety. Typically, agreements are for 36 months. A health professional who self-reports to HPSP and who fulfills the conditions of a participation agreement is not reported to the relevant licensing board.

Pharmacists, technicians, and interns may be reluctant to self-report to HPSP, possibly worried that reporting themselves to HPSP will somehow increase their chance of being disciplined by the Board. That is an unfounded concern. The reality is that the Board often becomes aware of situations involving pharmacists, technicians, and interns who divert CS or who consume alcohol in a manner that endangers patients – whether a person has self-reported to HPSP or not. Pharmacies that experience a loss of CS are required to report the loss to DEA by submitting a DEA 106 Loss Form. The pharmacies must simultaneously provide a copy of that form to the Board. If the form indicates that the loss has occurred because of employee pilferage, the Board always investigates the loss and obtains the name(s) of the employee(s) involved. Pharmacies are also required to report "any conduct that the [pharmacy] reasonably believes constitutes grounds for disciplinary action" by the Board.

In addition, licensees and registrants of the Board are required to self-report anything that the pharmacy that they work for would have to report to the Board. This means that pharmacists, technicians, or interns who have diverted drugs, abused alcohol, or who have a mental illness that is having an impact on their ability to safely practice, would have to report themselves to the Board. **However, the requirement to self-report for these issues can also be met by self-reporting to HPSP, rather than the Board.** Most individuals who self-report to HPSP and who successfully complete their participation agreement

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with HPSP will never be reported to the Board. (HPSP does have to report individuals to the Board if they have harmed a patient, forged or altered prescriptions, or in some way tampered with a medication that is given to a patient.)

As previously mentioned, the Board often becomes aware of situations for which self-reporting is required. If the investigation reveals that the individual has not self-reported to either HPSP or the Board, the failure to report becomes a separate ground for pursuing disciplinary action. Basically, the Board can discipline the individual for both the underlying behavior and for the failure to report. Also, while the Board considers every disciplinary case based on the facts of that case, it generally considers self-reporting to HPSP to be a positive sign that the individual is acknowledging his or her need for help and is taking appropriate action to get that help.

To learn more about HPSP and how to refer someone who may have an illness, call 651/643-2120, visit *www .hpsp.state.mn.us,* or write for information to:

HPSP
Energy Park Place
1380 Energy Park Lane, Ste 202
St Paul, MN 55108

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