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Minnesota Board of Pharmacy News

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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.

Prescription Monitoring Program – Required Registration

As mentioned in the February 2018 edition of the Board's *Newsletter,* state law requires all Minnesota-licensed pharmacists practicing within the state to register for and maintain a user account with the Minnesota Prescription Monitoring Program (PMP). That requirement went into effect on July 1, 2017. 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 a position that does not require licensure as a pharmacist (for example, a pharmacist who is also an attorney and who never practices pharmacy). **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 who believe that they do not need to register for an account because of one of the reasons listed above should notify the Board that they are not registering for an account and include the reason for not registering.** Notification can be provided to the Board by sending an email to pharmacy.board@state.mn.us.

Beginning July 1, 2018, one full year after the registration requirement went into effect, **the Board will open complaints against pharmacists who have not registered or who have failed to notify the Board that they are not required to be registered.** Once a complaint is opened, **pharmacists could be subject to possible disciplinary action, which might include a reprimand and a civil penalty** (ie, a fine).

Gabapentin and the Minnesota PMP

On August 1, 2016, a law went into effect that requires dispensers to report the dispensing of gabapentin to the PMP. Gabapentin is **not** a scheduled controlled substance (CS) in the state of Minnesota. However, per Minnesota Statute §152.126, gabapentin **must be reported** to the PMP.

Since gabapentin is not a CS, prescribers do not need a Drug Enforcement Administration (DEA) registration number to prescribe it. Minnesota Statute §152.11, Subdivision 2a states:

> 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 controlled substance in Schedule II, III, IV, or V. No person shall impose a requirement inconsistent with this subdivision.

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

For purposes of reporting gabapentin to the PMP, the prescriber's National Provider Identifier (NPI) should be utilized. The Board has confirmed with the NPI enumerator that is under contract with the Centers for Medicare and Medicaid Services that veterinarians are not eligible for an NPI because they do not meet the regulatory definition of a "health care provider" as defined per 45 Code of Federal Regulations 160.103. **Therefore, pharmacists and pharmacies should not ask veterinarians to provide an NPI number.**

The PMP is currently working with its vendor, Appriss Health, toward a solution for the reporting of gabapentin prescriptions when prescribed by veterinarians. Until a solution is available, pharmacies are asked to maintain a record of gabapentin prescriptions dispensed when prescribed by a veterinarian. Pharmacies may be asked to submit historical gabapentin data when a solution is made available.

The American Veterinary Medical Association recommends that pharmacists and pharmacy personnel ask veterinarians for their state license number in lieu of an NPI or DEA number for prescription processing. This is the best course in cases where non-controlled prescriptions are being dispensed.

Questions regarding the reporting of gabapentin to the PMP may be directed to PMP staff at Minnesota.PMP@state.mn.us or 651/201-2836.

Health Professionals Services Program

The Board investigates at least a dozen complaints each year against pharmacists and pharmacy 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. Fortunately, licensed and registered

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National Pharmacy Compliance News

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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 Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

FDA Advises on Opioid Addiction Medications and Benzodiazepines

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 at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

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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.

It has come to the Board's attention that pharmacists, technicians, and interns have become reluctant to self-report to HPSP, apparently worried that reporting themselves to HPSP will somehow increase their chance of being disciplined by the Board. That is an unfounded worry. 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 Form 106, Report of Theft or Loss of Controlled Substances. 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 (or names) of the employees 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 they work for would have to report to the Board. That means that a pharmacist, technician, or intern who has diverted drugs or abused alcohol or who has a mental illness that is having an impact on his or her ability to safely practice would have to report himself or herself 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 successfully complete their participation agreement 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 mentioned above, 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 grounds for pursuing disciplinary action. Basically, the Board can discipline the individual for both the underlying behavior and 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 the HPSP website at *www.hpsp.state.mn.us,* or write for information to:

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

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 five months left during which pharmacists can 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 can visit the Board's website *(www.pharmacy.mn.gov),* choose "Online Services" from the Quick Links menu, log in to the Board's system, and certify the completion of their CE. Alternatively, pharmacists 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'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 in to your Board online account.)

Treatment of Pediatric Patients With Opiate Dependency

Unfortunately, the epidemic of opioid abuse that the country is experiencing has resulted in a dramatic increase in the number of pregnant women who are addicted to narcotics and whose babies suffer from neonatal abstinence syndrome (NAS) after they are born. Those infants sometimes need to have a methadone taper prescribed for them, with the taper usually started while the infant is still hospitalized. The Board has learned that once these infants are discharged, outpatient pharmacies often refuse to fill prescriptions for the methadone required for the tapers. This refusal is based on federal regulations that, under most circumstances, prohibit pharmacies from dispensing methadone when it is being used to treat addiction.

The Board has confirmed with DEA that those regulations do not apply to infants who are suffering from NAS. Per a communication that the Board received from DEA: "These infants are not considered narcotic addicts. Therefore, the Narcotic Addict Treatment Act (NATA) does not apply to them. The physician treating neonatal opioid withdrawal is free to prescribe any opioid he or she feels would be most beneficial, based on his or her own clinical judgment, existing standards of practice, and the patient's response to therapy." Since physicians can prescribe opioids for these patients, pharmacies can legally dispense them so long as all other legal requirements for the prescription are met.

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