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Minnesota Board of Pharmacy News

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University Park Plaza • 2829 University Ave SE, Suite 530 • Minneapolis, MN 55414-3251
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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 the Board's 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.

Some of the most recent changes relate to actions taken by the federal United States Department of Health and Human Services that preempt state law. Those actions allow pharmacists to provide immunizations to children as young as three years of age. While federal preemptions remain in place, pharmacists will be able to order and administer any vaccine to individuals between the ages of three and 18 – provided that the immunization schedule developed by the Advisory Committee on Immunization Practices is followed. Several other requirements that must be met are described in the Board's COVID-19 FAQ document.

Another recent change to that document also involves vaccinations. Nothing in Minnesota Statutes or Rules requires that pharmacists give vaccinations only within a licensed pharmacy. However, pharmacists on duty in licensed pharmacies are expected to supervise technicians, interns, and other staff working in the pharmacy. Minnesota Rules 6800.2150, Subpart 1 states: "A pharmacy or satellite pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times that the pharmacy is open for the transaction of business except for brief absences of the pharmacist arising out of and in the course of pharmacy practice."

The length of time that it would take a pharmacist to leave the building to give a vaccination curbside or in the parking lot would not be considered a brief absence. That would particularly be the case if the pharmacy were advertising an influenza vaccination "clinic" – where multiple patients might simultaneously arrive for a vaccination.

Scheduling vaccination appointments or events in advance allows a pharmacy to continue providing this needed service to the public and to reduce potential exposure of certain staff to COVID-19. It also allows the site to anticipate and manage demand for pharmacist time so that proper scheduling and operation of the pharmacy, including supervision of technicians, can be maintained. The Board is aware of pharmacies that have opened early to give vaccinations at a time preannounced to patients. Pharmacies are also scheduling vaccination events, having pharmacists and technicians on duty strictly for the event, with other pharmacists and technicians working in the pharmacy to dispense prescriptions.

Pharmacist Continuing Education

Minnesota-licensed pharmacists are reminded that they should have certified completion of their continuing education (CE) by October 1, 2020, for the two-year CE cycle that ended on September 30, 2020. During every CE cycle, many pharmacists fail to certify completion of their CE, and they are automatically included in the Board's CE audit. Those pharmacists, and other pharmacists selected at random, will be required to submit proof of having completed the required number of CE hours. Those pharmacists selected for the audit who do not supply proof of having completed the CE

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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 Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

The complete list of changes is available through an July 2020 Drug Safety Communication.

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the announcement published in the *Federal Register,* this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at* www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fenta**NYL** patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fenta**NYL** patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fenta**NYL** patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fenta**NYL** patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge

from the ED, the resident was prescribed a fenta**NYL** patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fenta**NYL** patch. The ED physician reported that the resident had received "three small IV push doses" of fenta**NYL** in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fenta**NYL** patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fenta**NYL** patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking **HYDRO**codone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxy**CODONE** 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner education alone will not prevent life-threatening errors with fenta**NYL** patches. Yes, health care practitioners should be educated about safe prescribing, and their competency should be verified as a prerequisite to prescribing. But there will always be those who are unaware of the risks they take prescribing fenta**NYL** patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

Fenta**NYL** patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain in our *Targeted Medication Safety Best Practices for Hospitals*. In 2020, this best practice was incorporated into a new best practice (No.15) to verify and document the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fenta**NYL** patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fenta**NYL** patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, training, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the HHS Fact Sheet.

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders."

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requirement will not be allowed to renew their license (and will therefore not be able to practice) until the matter is resolved. If you have not yet certified completion of your CE for the cycle that ended on September 30, 2020, please contact the Board's office for assistance at 651/201-2825.

Health Professionals Services Program

The Board investigates at least a dozen complaints each year against pharmacists and technicians involved in the alleged diversion of controlled substances (CS), the abuse of alcohol, or the inability to safely practice due to a mental illness. The Board takes such complaints seriously because, if left untreated, substance abuse and other mental illnesses can put patients 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. Additional 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 may still be 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 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 US Drug Enforcement Administration (DEA) by submitting a DEA Form 106. 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 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 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

Pharmacy Technicians: Allowed Duties

It has come to the attention of Board staff that some pharmacies may still be allowing pharmacy technicians to perform duties that they are not legally allowed to perform. For example, some pharmacies may be allowing technicians to call long-term care facilities (LTCFs) or prescribers to clarify orders for patients who are residing in such facilities. Pharmacies may also be allowing technicians to call clinics to clarify orders for outpatients – or to prepare and send faxes to clinics, asking for clarifications about prescriptions. None of those activities are allowed under Minnesota Statutes and Rules.

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Technicians can obtain demographic information from LTCFs, such as age, birthdate, address, and insurance information. They can take refill requests from such facilities so long as the facility is only requesting that existing orders be refilled, and no changes are being made to those orders. Similarly, they can take a refill authorization from a clinic or prescriber so long as no changes are made to the prescription. However, technicians cannot take new orders, and they cannot call for clarification of orders.

Minnesota Statutes §151.01, Subdivision 15a defines "pharmacy technician" to mean (emphasis added) "a person not licensed as a pharmacist or registered as a pharmacist intern, who has been trained in pharmacy tasks that **do not require the professional judgment of a licensed pharmacist. A pharmacy technician may not perform tasks specifically reserved to a licensed pharmacist."** Minnesota Statutes §151.102, Subdivision 1 states, in part (emphasis added): "A pharmacy technician may assist a pharmacist in the practice of pharmacy by performing **tasks that are not reserved to, and do not require the professional judgment of, a licensed pharmacist."**

Minnesota Rules 6800.3100 specifically reserves the receipt of verbal orders to pharmacists and pharmacist interns. That includes both new orders and clarification of orders. That rule also reserves verification of the validity and propriety of all prescription drug orders to pharmacists and interns. In addition, the Board considers clarification of orders to require the professional judgment of a pharmacist. Consequently, technicians may not contact LTCFs, clinics, or prescribers to clarify nursing home orders or outpatient prescriptions. Technicians can fax a clarification request, but only if a pharmacist or pharmacist intern has prepared the request.

Note that the Board has already disciplined at least one pharmacist for allowing a technician to receive verbal clarification of an order from an LTCF nurse, assessing a $2,500 civil penalty and requiring the completion of additional CE. In that case, a patient experienced a significant adverse reaction after receiving a tenfold overdose of a medication.

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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