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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.

2016 Legislation Concerning the Practice of Pharmacy

The following is a summary of legislation passed during the 2016 session of the Minnesota Legislature that affects the practice of pharmacy. Additional information, including the actual legislation that was passed, can be found on the Board website.

Collection of Pharmaceutical Waste by Pharmacies

Effective May 20, 2016, a pharmacy licensed by the Board and located in Minnesota may collect a legend drug from an "ultimate user" (ie, from a member of the public), or from a long-term care facility (LTCF) on behalf of an ultimate user (ie, patient or resident) who resides or resided at the LTCF, for the purpose of disposing of the legend drug as pharmaceutical waste. In order to collect drugs for disposal as pharmaceutical waste, a pharmacy must comply with Drug Enforcement Administration (DEA) regulations for the collection of controlled substances (CS) by pharmacies. A pharmacy must comply with those regulations for all drugs collected – even for non-CS. In addition, pharmacies must comply with statutes and rules administered by the Minnesota Pollution Control Agency (MPCA).

Although this law became effective on May 20, 2016, pharmacies cannot begin collecting unwanted pharmaceuticals for disposal until they meet certain DEA and MPCA requirements. Pharmacies should not begin collecting pharmaceuticals until those requirements are met. The Board is working with the MPCA to develop a *Guidance for Collecting Pharmaceuticals from Households and Long Term Care Facilities (LTCF).* This document will include all of the details that pharmacies that want to collect pharmaceuticals for disposal will need to know. However, here are a few points to consider:

- A pharmacy will need to modify its DEA registration to become an authorized collector.
- A pharmacy will also need to ensure it has obtained a Hazardous Waste Identification Number from the MPCA for each separate collection site, including LTCFs.
- A pharmacy must submit a Household Pharmaceutical Consolidation Site Application to the MPCA or obtain the equivalent license from its Metro County office.
- Pharmacies may only collect pharmaceuticals inside their pharmacy site or inside an LTCF where they provide pharmacy services. Pharmacies may not conduct off-site "take-back" events nor install drop boxes off site or that are accessible from outside the pharmacy.
- Pharmaceuticals must be collected in collection receptacles that meet the requirements of the above-mentioned DEA regulations. Patients or LTCF staff must place the unwanted pharmaceuticals into the collection receptacles. Pharmacy staff may not take pharmaceuticals directly from the public or from LTCF staff and place them into the receptacles.
- Other businesses and law enforcement agencies may not bring discarded pharmaceuticals they have collected to a pharmacy for disposal.

Prescription Monitoring Program

The following changes were made related to the Board's Prescription Monitoring Program (PMP). These changes are effective August 1, 2016, unless otherwise noted.

- Gabapentin was added to the list of drugs for which prescriptions must be reported to the PMP.
- All health licensing boards were authorized to have access to PMP data for the purpose of investigating bona fide complaints involving their licensees and registrants. Boards may request data from the PMP when they are investigating complaints that allege that a specific licensee is impaired by use of a drug for which data is collected by the PMP, has engaged in a CS crime, or has engaged in doctor shopping. In addition, boards that license prescribers can request data from the PMP when they are investigating complaints that allege that a specific licensee is inappropriately prescribing CS. (Previously, only the Board of Pharmacy had the authority to access PMP data when investigating complaints.)
- Prescribers were authorized to obtain PMP data, without consent, for additional situations in which they are providing care and have reason to believe that the patient is potentially abusing a CS. That belief must be based on the presence of clinically valid indications. The Board fought to have similar language included for pharmacists, but certain members of the House of Representatives would not accept that language.

continued on page 4

FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.*

More Selected Medication Safety Risks to Manage in 2016

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as 154 mEq/0.9% = x/3% and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag (77 mEq/0.9% = x/3%).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,[1-5] and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.[6] The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that

most of these errors happened within the first 14 days after discharge.[5] The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).[4]

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

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USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings,* has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at *www.usp.org* in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium.*

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the February 2016 Drug Info Rounds video, "Emergency Preparedness – Keeping Medications Safe," pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency's effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency's approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.*

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA's Drug Safety Communication announcement, available at *www.fda.gov/Drugs/DrugSafety/ucm489676.htm.*

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus' facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.*

continued from page 1

Consequently, pharmacists may access the PMP when:

- ◊ They are dispensing or considering the dispensing of a CS; or
- ◊ They are consulted by a prescriber who is requesting data.

- ♦ A "sunset" provision that would have ended the ability of the Board to send out Controlled Substance Insight Alerts (CSIAs) to prescribers and pharmacies was removed. The Board's PMP pharmacist consultant will continue to send CSIAs to prescribers and pharmacists when data suggests that an individual may be engaging in doctor shopping.
- ♦ Prescribers and pharmacists practicing within Minnesota were required to register as PMP users (but were not required to actually use the PMP). By July 1, 2017, every prescriber licensed by a Minnesota health licensing board and practicing within this state who is authorized to prescribe CS for humans and who holds a current registration issued by DEA, and **every pharmacist** licensed by the Board and **practicing within the state, must register and maintain a user account with the PMP.** Pharmacists are strongly encouraged to establish a PMP account as soon as possible. Online registration is available at *http://pmp.pharmacy.state.mn.us/pharmacist-rxsentry-access-form.html*.
- ♦ The Board was allowed to keep the prescription data that it collects, in an identifiable manner, so that a study of the effectiveness of the PMP can be conducted. Data collected from January 1, 2015, through December 31, 2018, will be kept in an identifiable manner through December 31, 2019. That data will then be destroyed, and subsequently collected data will be destroyed one year from the date on which it was provided to the Board.
- ♦ Language was added to clarify that the PMP Advisory Task Force does not expire.

Naloxone

The Board proposed legislation that would have allowed pharmacists to directly prescribe naloxone. Unfortunately, the legislation was vigorously opposed by the Minnesota Medical Association. The following provisions were ultimately passed and became effective May 20, 2016.

- ♦ Existing law already allows pharmacists to work under a protocol issued by a practitioner when initiating, modifying, managing, or discontinuing any drug. Consequently, no change in law was necessary to allow pharmacists to work under a protocol with a practitioner and to prepare a legally valid prescription for naloxone. Nevertheless, the Board is required to develop an opiate antagonist protocol that practitioners will be able to use when authorizing pharmacists who are working under that protocol to prepare legally valid prescriptions for naloxone. Note that pharmacists and practitioners, other than medical consultants for community-based health boards or practitioners working for the Minnesota Department of Health, are not required to use the protocol developed by the Board.
- ♦ The commissioner of health is required to provide the following items to medical consultants who are working for community-based health boards:
  - ◊ Educational materials concerning the need for, and opportunities to provide, greater access to opiate antagonists;
  - ◊ The opiate antagonist protocol developed by the Board; and
  - ◊ A notice of the liability protections related to the prescribing of naloxone pursuant to a protocol that are extended to cover the use of the Board's opiate antagonist protocol by community health board (CHB) medical consultants.

The intent is to encourage these medical consultants to enter into protocols with local pharmacists who want to provide naloxone per protocol. However, nothing requires these medical consultants to enter into a protocol with any pharmacist.

- ♦ The commissioner of health is allowed, but not required, to designate a practitioner (prescriber) to enter into the Board's naloxone protocol with pharmacists practicing within one or more community health service areas, but only at the request of the applicable CHB. A CHB must make the request to the commissioner by October 1 for the subsequent calendar year. So, if the medical consultant for a CHB does not want to enter into a protocol with pharmacists and if the CHB does not request that a practitioner employed by the Department of Health enter into a protocol, pharmacists interested in providing naloxone by protocol would need to find some other willing prescriber.
- ♦ Immunity related to the prescribing of naloxone per protocol was extended to both the commissioner of health and to the designated practitioner when prescribing according to the protocol under this subdivision. The commissioner of health and the designated practitioner are both deemed to be acting within the scope of state employment when prescribing according to the protocol developed by the Board.

CS Scheduling

Over a dozen synthetic "designer" stimulants, hallucinogens, and cannabinoids were added to Schedule I. Eluxadoline (Viberzi™), a federal Schedule IV drug, was added to Minnesota's Schedule IV.

Temporary Suspension of Licenses

Language was amended in Minnesota Statutes Chapter 214 to clarify the circumstances under which health licensing boards can temporarily suspend a registration or license when a regulated person has violated a statute or rule that the health licensing board is empowered to enforce, and continued practice by the regulated person presents an imminent risk of serious harm. The procedures that a board must follow when issuing a temporary suspension were also clarified.

Board's Appropriation

The Board was granted a supplemental increase in its appropriation of $115,000 for fiscal year 2016 and $145,000 for fiscal year 2017. The increased expenditures can be covered with existing revenue, so no fee increase was necessary.

90-Day Supplies of Prescription Drugs

Other groups pursued legislation that allows pharmacists to dispense a 90-day supply of a prescription drug under certain circumstances even when the prescription was written for a smaller quantity. This provision is not effective until August 1, 2016. Due to ambiguity in the language, the Board may have to issue a guidance document. Any such guidance will be issued before that date.

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