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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.

Board Adopts Work Conditions Rule

The Board published the following notice in the May 30, 2017 edition of the *State Register* – the last action needed to officially adopt the Board's proposed work condition rule:

> **Adopted Permanent Rules Relating to Pharmacy Working Conditions.**
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> The rules proposed and published at State Register, Volume 41, Number 12, pages 355-357, September 19, 2016 (41 SR 355), are adopted as proposed.

The rule went into effect on July 1, 2017. The rule:

- Prohibits pharmacies located within Minnesota from requiring pharmacists, pharmacist-interns, and pharmacy technicians to work more than 12 consecutive hours within a day (24-hour period).
- Requires pharmacies to allow pharmacists, pharmacist-interns, and pharmacy technicians to take a 30-minute, uninterrupted break if they work more than six continuous hours per day.
- Requires pharmacies to allow pharmacists, pharmacist-interns, and pharmacy technicians adequate time during each four-hour work period to use the nearest conveniently located restroom.
- Allows, but does not require, pharmacies to close when a pharmacist is on break and away from the licensed pharmacy space.
- Establishes requirements for the operation of the pharmacy and the dispensing of filled prescriptions if a pharmacy remains open when the pharmacist is on break and away from the pharmacy.
- Creates an exception for bona fide emergencies.

A copy of the adopted rule and additional documents related to the rulemaking process can be found on the Board website at *https://mn.gov/boards/pharmacy/statutes/rules.jsp*. In addition, the full text of the rule can be found on the Minnesota Office of the Revisor of Statutes website at *https://www.revisor.mn.gov/rules/?id=6800.2160.*

Please submit any questions you may have about the rule to the Board's main email address, at pharmacy.board@state.mn.us, for routing to the appropriate staff person. After Board staff has received and answered questions about this rule, the Board will develop a Frequently Asked Questions document that will be placed on the Board website. One question that Board staff has already been receiving is: "Are pharmacists, technicians, and interns required to take breaks?" No, they are not. Pharmacies must allow them to take breaks, as specified in the rule, but pharmacists, technicians, and interns can decline to take the breaks to which they are entitled. However, the Board would most likely take a very dim view of any attempts to coerce individuals to "voluntarily" not take breaks. Similarly, the rule does not prohibit pharmacists, interns, and technicians from working shifts that are longer than 12 hours – so, they can volunteer to do so, as long as they are not coerced into volunteering.

2017 Legislation Affecting the Practice of Pharmacy

Several pieces of legislation were passed by the Minnesota Legislature during the 2017 Regular and First Special Sessions and signed into law by Governor Mark Dayton. A document that contains the changes in statutes can be found on the Board website, but highlights are as follows:

Biosimilar Substitution. A change to Minnesota Statutes §151.21 allows pharmacists to make substitutions, without the prescriber's approval, when biologic products are prescribed and a United States Food and Drug Administration (FDA)-approved biosimilar product is available. Note that a pharmacist may not substitute a biological product, without the prescriber's approval, unless FDA has determined the substituted biological product to be interchangeable with the prescribed biological product. In addition, within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee must communicate to the prescriber the name and manufacturer of the biological product dispensed. However,

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WHO Launches Global Patient Safety Challenge on Medication Safety

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at *http://who.int/mediacentre/news/releases/2017/medication-related-errors/en.*

Continuous Quality Improvement and Patient Safety Organizations

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.*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy.*

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda,* which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit *https://www.pso.ahrq.gov/faq.*

NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at *www.ncpdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf.* Additional information for pharmacists about emergency preparedness is available on the NCPDP website at *www.ncpdp.org/Resources/Emergency-Preparedness.*

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at *www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm.*

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at *www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm.*

FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a "bulk drug substance" and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at *www.fda.gov/Drugs/DrugSafety/ucm502075.htm,* FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA's website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf* and *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf.*

APhA Resource Guide Applies JCPP Pharmacists' Patient Care Process to Immunization Services

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists' Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists' Patient Care Process to Immunization Services.* "[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation," indicates the APhA guide. For more information, visit the APhA Immunization Center at *www.pharmacist.com/immunization-center.*

CPE Training on Older Adult Fall Prevention Available Online

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, "STEADI: The Pharmacist's Role in Older Adult Fall Prevention," visit the CDC website at *www.cdc.gov/steadi/training.html* for more information.

New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Combat Methamphetamine Epidemic Act," pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), 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 Presents Series of CE Webinars for Students and Clinicians

FDA's Division of Drug Information in the CDER presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars.*

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this communication does not have to happen if there is no FDA-approved, interchangeable biologic product. There are several ways in which the information can be communicated to the prescriber. For example, simply billing a prescription to a pharmacy benefit manager (PBM) is considered communicating the dispensing to the prescriber, since prescribers have access to patient records maintained by PBMs. As with any other drug, a pharmacist cannot make a substitution if the prescriber has indicated that the prescription is to be dispensed as written.

Labeling of Opiate Prescriptions. Minnesota Rules have long required that systemically administered controlled substances (CS), and other drugs deemed appropriate in the professional judgment of the pharmacist, have special labeling (when dispensed to adults for outpatient use). The labeling of all such drugs must include: "Caution: Taking this drug alone or with alcohol may impair your ability to drive." CS labels must also be labeled: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

Legislation passed this year adds an additional labeling requirement for opiates. Whenever a prescription drug containing an opiate is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug must prominently display on the label or container a notice that states "Caution: Opioid. Risk of overdose and addiction." This can be done as part of the main prescription label, or auxiliary labels can be used.

Quantity Limits for Opiates Prescribed for Acute Dental or Refractive Surgery Pain. When used for the treatment of acute dental pain or acute pain associated with refractive surgery (eg, LASIK), prescriptions for opiate or narcotic pain relievers are limited to a four-day supply. The quantity prescribed needs to be consistent with the dosage listed in the professional labeling for the drug that has been approved by FDA. (For example, if the FDA-approved labeling for a drug is such that the maximum recommended dose amounts to eight tablets per day, a prescriber cannot prescribe 16 tablets per day). **However,** if in the professional clinical judgment of a practitioner, more than a four-day supply is required to treat a patient's acute pain, then the practitioner may issue a prescription for the quantity needed to treat such acute pain. Pharmacists will need to do additional evaluation of prescriptions for opiate pain relievers received from dentists and ophthalmologists if the quantity exceeds a four-day supply. That might have to include a call to the prescriber to find out if the drug was prescribed for acute or chronic pain, if it was prescribed for refractive surgery or for some other ophthalmic condition, and if the prescriber has determined that a larger quantity is necessary when the pain is acute.

Information About Legislation That Provides Pharmacists With Opportunities to Volunteer. Legislation was passed that directs the Minnesota Commissioner of Health to form a Palliative Care Advisory Council and to issue grants to establish Opioid Abuse Prevention Pilot Projects around the state. Pharmacists are among the health professionals who can serve on the Palliative Care Advisory Council. The opioid abuse pilot projects must "establish multidisciplinary controlled substance care teams that may consist of physicians, pharmacists, social workers, nurse care coordinators, and mental health professionals." Interested pharmacists should contact the Minnesota Department of Health for additional information.

The Health Professionals Services Program

The Board typically receives several dozen complaints each year against pharmacists, pharmacy technicians, and pharmacist-interns that allege diversion of CS, 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 protects the public by providing monitoring services to regulated health care professionals whose illnesses may impact their ability to practice safely. The stigma associated with illnesses such as substance abuse and mental health disorders can make health care practitioners hesitant to seek treatment. Confidential monitoring increases the likelihood that professionals will seek treatment early, before clinical skills are compromised. And monitoring improves treatment compliance, which can lead to successful outcomes.

HPSP carries out its mission by promoting early intervention, diagnosis, treatment, and monitoring for health professionals who have potentially impairing conditions. HPSP evaluates professionals and, if necessary, enters into treatment agreements with them. HPSP monitors treatment progress, work quality, medications, attendance at support groups, and other relevant matters.

Minnesota Statutes §151.072 states, in part, that a "licensee or registrant of the board shall report to the board personal knowledge of any conduct that the person reasonably believes constitutes grounds for disciplinary action . . . by any pharmacist, pharmacist intern, pharmacy technician . . . including any conduct indicating that the person . . . may be medically or physically unable to engage safely in the practice of pharmacy or to carry out the duties permitted to the person by this chapter or the rules of the board." The same section also requires licensees or registrants of the Board to self-report such conduct. However, language in Minnesota Statutes §214.33 allows individuals to fulfill these reporting obligations by filing a report with HPSP, rather than the Board, when the licensee or registrant being reported "has the inability to practice with reasonable skill and safety by reason of illness, use of alcohol, drugs, chemicals or any other materials, or as a result of any mental, physical, or psychological condition." Note that in certain circumstances, employers must report the diversion or theft of drugs directly to the Board. But even in such circumstances, it would be potentially beneficial to also make a report to HPSP.

To learn more about HPSP and how to refer someone who may have an illness, call 651/642-0487, visit the HPSP website at *https://mn.gov/boards/hpsp,* or write for information to Health Professionals Services Program, 1380 Energy Lane, Suite 202, Saint Paul, MN 55108.

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