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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.

USP Chapter <800>

The United States Pharmacopeia (USP) published the new General Chapter <800> on February 1, 2016, in the United States Pharmacopeia and the National Formulary (USP–NF) in the First Supplement to USP 39–NF 34. Chapter <800> sets updated standards for the safe handling of hazardous drugs (HDs). For frequently asked questions (FAQs) and a link to the chapter, please visit *www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings.* Here are a few key points, mostly taken verbatim from the FAQs:

- A hazardous drug is any drug identified as hazardous or potentially hazardous by the National Institute for Occupational Safety and Health (NIOSH) on the basis of at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing HDs in structure or toxicity. NIOSH maintains a list of antineoplastic drugs and other HDs used in health care settings found at *https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf.*
- Chapter <800> was written to protect all workers, patients, and the general public who may be accessing facilities where HDs are prepared. This includes, but is not limited to, pharmacists, technicians, nurses, physicians, physician assistants, home health care workers, veterinarians, and veterinary technicians. If any workers come in contact with HDs, they must receive HD training and be assessed for an understanding of the training. All personnel who handle HDs are responsible for understanding the fundamental practices and precautions and for continually evaluating these procedures and the quality of final HDs to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and patient-care environment.
- The chapter applies to all health care personnel who handle HD preparations and all entities that store, prepare, transport, or administer HDs (eg, pharmacies, hospitals and other health care institutions, patient treatment clinics, physicians' practice facilities, and veterinarians' offices).

The USP Compounding Expert Committee approved a delayed official implementation date of July 1, 2018, to allow entities additional time to implement the standard. With the delayed official date, entities will have had more than two years to implement this new standard by the time it becomes effective. Also, USP General Chapter <795>, which has been in place for over a decade, already requires HDs to be "stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel." (In fact, the Board has issued disciplinary orders against two pharmacies in which progesterone, an HD, was being compounded in a manner not consistent with Chapter <795>.) Consequently, the Board will expect compliance with Chapter <800> by July 1, 2018, unless USP further delays the implementation date. Pharmacies would be well-advised to immediately begin working toward compliance with Chapter <800> if they have not already done so.

Drug Utilization Review and Patient Profile Review

On December 15, 2016, the *Chicago Tribune* published the story "Pharmacies miss half of dangerous drug combinations." According to the article, "the Tribune tested 255 pharmacies to see how often stores would dispense dangerous drug pairs without warning patients. Fifty-two percent of the pharmacies sold the medications without mentioning the potential interaction, striking evidence of an industrywide failure that places millions of consumers at risk." Reporters brought in prescriptions for dangerous combinations such as clarithromycin and simvastatin; colchicine and verapamil; and tizanidine and ciprofloxacin. While the reason these interactions were missed is not known to the Board, it is at least possible that the pharmacists who dispensed these dangerous combinations may have either not completed patient profile reviews and drug utilization reviews (DURs) at all or hurried through them. In addition, it is possible that the counseling done when the prescriptions were dispensed was not properly conducted.

Pharmacists are reminded that Minnesota Statutes and Rules require the completion of appropriate patient profile reviews and

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National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
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FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at *www.ecfr.gov.*

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at *www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf.* FDA provides more information online at *www.fda.gov/Drugs/DrugSafety/ucm524320.htm.*

Selected Medication Risks to Manage in 2017

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.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.[1] Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.[1,2] This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.[1,2]

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.[3,4] Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.[4] Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.[4] Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.[4] Medication rooms should provide illumination at 100 fc.[4] Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy[3] and should be used on mobile medication carts (including those used with bar code medication verification systems)[4] and near ADCs.

References:

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2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at *www.dea.gov/divisions/hq/2016/hq100416.shtml* and in the final order available at *https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf*.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, "Pharmacists: On the Front Lines," offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at *www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf*.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm*.

FDA's Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information 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 drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars*.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will "alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse." In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at *www.fda.gov/Drugs/DrugSafety/ucm526206.htm*.

Latest FDA Drug Info Rounds Training Videos Available

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, "Extortion Scam," pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA's 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*.

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DURs for **every** prescription dispensed. Minnesota Statutes §151.06, Subdivision 1(b), which generally authorizes the Board to promulgate rules, more specifically states that the "board shall adopt rules regarding prospective drug utilization review and patient counseling by pharmacists. A **pharmacist** in the exercise of the pharmacist's professional judgment, upon the presentation of a prescription by a patient or the patient's caregiver or agent, **shall** perform the prospective drug utilization review required by rules issued under this subdivision."

Minnesota Rules 6800.3100, Subpart 3 requires pharmacists to "review the patient's medication profile for purposes of conducting a prospective drug review and checking the accuracy of the addition to the profile of the medication dispensed." Minnesota Rules 6800.3110, Subpart 1 requires pharmacies to maintain a patient profile record system designed for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed medication at the time a prescription drug order is presented for dispensing. Minnesota Rules 6800.3110, Subpart 3 requires that "[u]pon receiving a prescription drug order, a pharmacist **shall examine the patient's profile record** before dispensing the medication to determine the possibility of a harmful drug interaction or reaction." Minnesota Rules 6800.3110, Subpart 4 reads (emphasis added):

> **Drug use review for patients.** Upon receiving a prescription drug order, or prescription refill request for a patient, **a pharmacist shall examine the patient's profile record and conduct a prospective drug review** to identify:
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> A. overutilization or underutilization;
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> B. therapeutic duplication;
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> C. drug-disease contraindications;
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> D. drug-drug interactions;
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> E. incorrect drug dosage or duration of drug treatment;
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> F. drug-allergy interactions; or
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> G. clinical abuse or misuse.
>
> **Upon recognizing any of these drug-related problems, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber.**
>
> For the purpose of meeting the requirements of this subpart, a pharmacist may rely on computerized medication profile review, provided that it includes all medication dispensed by the pharmacy for the patient during at least the preceding six months. **The pharmacist-in-charge must develop procedures for handling alerts generated by the computerized medication profile review** and include these procedures in the written procedures required under part 6800.3950. **Only a pharmacist or a pharmacist-intern working under the immediate and direct supervision of a pharmacist may override the alerts.**

Please note that a technician may **never** override **any** DUR alert no matter the severity level. The best standard of practice is to use dispensing software that places a hard stop on DUR alerts that **only** a pharmacist can personally override through the use of biometrics, a personalized barcode, or a password. If a password is used, the pharmacist should **never** share it with anyone else.

Minnesota Rules 6800.0910, Subpart 2 describes the procedures that must be followed when counseling is provided to a patient. It states, in part: "Upon receipt of a new prescription, **following a review of the patient's record,** a pharmacist shall personally initiate discussion of matters which in the professional judgment of the pharmacist will enhance or optimize drug therapy with each patient or the agent or caregiver of the patient." Here again, the rule requires a pharmacist's review of the patient's record (ie, profile) prior to the mandatory counseling that must be provided. That review can be done as part of the previously mentioned profile review.

Pharmacists and owners of pharmacies are reminded that Minnesota Rules 6800.2250, Subpart 1(H) makes it unprofessional conduct for a pharmacy or pharmacist to violate any law, rule, regulation, or ordinance of the state or any of its political subdivisions, including the Board, or the US government, or any agency thereof relating to the practice of pharmacy. To the extent that the statutes and rules related to patient profiles and DURs are violated, both the pharmacy and the pharmacist involved can be subject to possible disciplinary action.

When conducting inspections, the Board's pharmacy surveyors sometimes observe that pharmacist staffing levels seem to be inadequate given the volume of prescriptions dispensed and the other tasks, such as immunizations, that the pharmacists are required to perform. Therefore, the Board encourages pharmacy owners to carefully consider prescription volume, plus the non-dispensing duties that pharmacists have to perform, when establishing staffing levels to help ensure that vital activities such as DURs, profile reviews, and counseling can be completed appropriately.

Update on Proposed Work Condition Rules

As reported in earlier editions of this *Newsletter,* the Board has been working on proposed new rules that will prohibit pharmacies from requiring pharmacists, pharmacy technicians, and pharmacist interns to work more than 12 continuous hours per day; require pharmacies to allow these individuals to take a 30-minute break if they work longer than six hours; and require pharmacies to allow these individuals "adequate time from work within each four consecutive hours of work to utilize the nearest convenient restroom." Pharmacies will be allowed to remain open while a pharmacist is on break, provided certain conditions are met.

The Board held a rules hearing before Administrative Law Judge Perry M. Wilson on October 19, 2016. After the requisite post-hearing comment periods, Judge Wilson issued his report on December 16, 2016, concluding that the "Board has established that it has the statutory authority to adopt the proposed rules and that the proposed rules are needed and reasonable." Judge Wilson has recommended that the Board adopt the proposed rule. In order to do so, the Board has to get final approval from the governor and then has to approve a notice and order adopting the rule. The Board anticipates that it will be able to issue the notice and order at its February 1, 2017 meeting. The rule will go into effect on July 1, 2017. Additional information can be obtained on the Board's website at *http://mn.gov/boards/pharmacy/statutes/rules.jsp* (scroll down to the bottom of the page).

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