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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
www.pharmacy.mn.gov

Disciplinary Activity

At its January and March meetings, the Minnesota Board of Pharmacy took disciplinary action against the following **pharmacies, pharmacists,** and **technicians** in cases related to practicing or working without a current license or registration.

Furman, Melanie Grimes, Registration #728742. Failed to renew registration by December 31, 2013; worked for approximately nine weeks without an active registration; reprimand and $60 civil penalty.

Omnicare of Minnesota, License #261366. Allowed a technician to work without an active registration for a period of approximately 10 weeks; reprimand and $225 civil penalty.

Paschke, Jonathan J., License #119459. While serving as a pharmacist-in-charge, allowed a technician to work without an active registration for approximately 15 shifts spread out over a period of time; reprimand.

Reller, Ruth A., Registration #728811. Failed to renew registration by December 31, 2013; worked for approximately eight weeks without an active registration; reprimand and $50 civil penalty.

The Board took the following disciplinary actions against **pharmacies** at its January and March meetings.

Abrams Royal Pharmacy, License #263379. The Board and Abrams Royal Pharmacy stipulated to the facts that, prior to February 26, 2013, licensee did not have patient-specific prescriptions before shipping sterile compounded products into Minnesota; licensee did not use United States Pharmacopeia (USP) standards when extending beyond-use dates; and licensee's compounding log did not include unique identifiers of all individuals involved in the compounding process. Abrams Royal did not admit to wrongdoing or violation of any statutes or rules that the Board is empowered to enforce but, to avoid the expense of further litigation, agreed that the Board could impose disciplinary action. Consequently, the Board accepted the voluntary surrender of Abrams Royal's license.

Walgreens #2661, License #260583. This pharmacy was compounding hazardous drugs, including progesterone extended-release capsules. The pharmacy did not have paper copies of either USP Chapter <795> or of the corporate policies and procedures related to the compounding of hazardous drugs; staff on duty were unable to access electronic copies. The pharmacy did not have a Class I Biological Safety Cabinet for the preparation of hazardous drugs. The pharmacy did not supply personnel with appropriate protective equipment for use during the compounding of hazardous drugs. Personnel were not properly trained on all aspects of compounding hazardous drugs. Licensee subsequently took steps to address these issues. Consequently, the Board reprimanded the licensee and imposed a civil penalty in the amount of $5,000.

Walgreens #3293, License #261126. The Board investigated a complaint that alleged that a dispensing error had occurred at this pharmacy. The investigation confirmed that the error had occurred and further revealed evidence that counseling was not being completed on all new prescriptions, as required by Minnesota Rules. Consequently, the Board reprimanded the licensee and imposed a civil penalty in the amount of $2,500.

Walgreens #06056, License #261960. This pharmacy was compounding hazardous drugs, including progesterone extended-release capsules. An inspection of the pharmacy revealed gaps in compliance with USP Chapter <795> standards for nonsterile compounding. In the absence of a Class I Biological Safety Cabinet, respirators were not provided to staff. Hazardous and non-hazardous drugs were found comingled in storage, with some hazardous drugs stored on upper shelves. Beverages were in the compounding area and hazardous drug waste containers were not available. Licensee subsequently took steps to address these issues. Due to the above violations, the

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FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm*.

2014-2015 Targeted Medication Safety Best Practices for Hospitals

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.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp)*.

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf*.

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_X$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

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. The latest Drug Info Rounds videos are as follows.

- In "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

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. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

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Board reprimanded the licensee and imposed a civil penalty of $5,000.

Walgreens #13690, License #263687. The Board investigated a complaint that alleged that dispensing errors had occurred at this pharmacy. The investigation confirmed that the errors had occurred and further revealed evidence that Minnesota Rules concerning counseling were not being followed. Consequently, the Board reprimanded the licensee and imposed a civil penalty in the amount of $2,500.

Wedgewood Village Pharmacy, License #264477. Licensee is not, nor has it ever been licensed as a drug wholesaler by the Board. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. However, beginning January 7, 2013, licensee began dispensing drugs only pursuant to patient-specific prescriptions. Licensee asserted that it was acting on a good-faith interpretation of Minnesota law, specifically Minnesota Statutes §151.01, Subdivision 30 (2012). The Board asserts that Minnesota law prohibited licensee from shipping drugs for office use without being licensed as a wholesaler. Licensee, for purposes of settlement of the matter, and for no other purposes civil, administrative, or criminal, agreed that the Board could impose discipline in the form of a reprimand and a $10,000 civil penalty.

The Board took the following disciplinary actions against **pharmacists** at its January and March meetings.

Caruso, Gregory R., License #114640. Mr Caruso admitted that on March 20, 2014, he arrived for his shift at a Minnesota pharmacy impaired by alcohol. He avers that at no time on that day did he provide pharmacy services to his employer, nor did he interact with customers on or off duty with his employer. He was terminated by his employer for reporting to work impaired by alcohol. He voluntarily underwent chemical dependency treatment and also voluntarily enrolled in the Health Professionals Services Program (HPSP). While Mr Caruso denied that his behavior on the date in question endangered public health, he acknowledged that it constituted a violation of Minnesota Statutes §151.06, Subdivision 1(a)(7)(iv)(2013). That being sufficient grounds to take disciplinary action, the Board issued a stipulation and consent order suspending Mr Caruso's license, but staying the suspension upon condition that he successfully complete his participation agreement with HPSP.

Dirks, Philip A., License #116958. Mr Dirk's employment with a Minnesota pharmacy was terminated in 2012 after he was caught diverting controlled substances (CS) and other abusable drugs. He also pleaded guilty to fifth-degree possession of a CS. On several dates in July and August 2014, toxicology specimens submitted as part of Mr Dirk's participation in the HPSP tested positive for alcohol. He was subsequently discharged from HPSP for noncompliance. Consequently, the Board issued a stipulation and consent order suspending his license to practice pharmacy for an indefinite period of time.

McMillen, Amanda J., License #119777. Ms McMillen's employment with a Minnesota pharmacy was terminated after she admitted to diverting CS. In April 2014, she voluntarily enrolled in HPSP. On June 12, 2014, she pleaded guilty to fifth-degree possession of a CS. Consequently, the Board issued a stipulation and consent order suspending Ms McMillen's license, but staying the suspension upon condition that she successfully complete her participation agreement with HPSP.

Shores, Anissa J., License #118071. Ms Shores' employment with a Minnesota pharmacy was terminated after the pharmacy determined that she had diverted 67,000 doses of both controlled and non-controlled drugs. On October 29, 2014, she pleaded guilty in federal court to a felony charge of obtaining a CS by fraud. Consequently, the Board issued a stipulation and consent order for voluntary surrender of her license to practice pharmacy.

The Board took the following disciplinary actions against **technicians** at its January and March meetings.

Mulenga, Cosmos B., Registration #728739. Mr Mulenga admitted that he stole $180 from his employer's cash register. Consequently, the Board adopted a stipulation and consent order that reprimanded the registrant, imposed a civil penalty of $180, and required him to show proof of having made restitution to his employer in the same amount.

Sogla, Esther B., Registration #718021. Ms Sogla submitted to a random toxicology screening while being employed as a pharmacy technician. The sample provided by Ms Sogla tested positive for marijuana. She refused to submit a second sample, as requested by her employer, and was terminated from her employment. Consequently, the Board accepted the voluntary surrender of her registration and issued a stipulation and consent order for voluntary surrender.

DEA Registration Numbers and National Provider Identifiers

Various practitioners have complained to the Board office that pharmacies are calling to request a Drug Enforcement Administration (DEA) registration number even when the prescription in question is not for a CS. In addition, veterinarians have called to complain that pharmacies are indicating that they cannot fill prescriptions without having the veterinarian's National Provider Identifier (NPI).

Minnesota Statutes §152.11, Subdivision 2a states that "A prescription need not bear a federal drug enforcement administration registration number that authorizes the prescriber to prescribe controlled substances if the drug

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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 be requesting DEA registration numbers for non-CS prescriptions.**

The Centers for Medicare and Medicaid Services addresses the issue of veterinarians and NPIs on its website with a FAQ that states, in part, "Veterinarians are not eligible for NPIs because they do not meet the regulatory definition of 'health care provider' as defined at 45 CFR 160.103 . . . Please be advised that just because the Healthcare Provider Taxonomy Code Set has a code for 'Veterinarian' does not mean a veterinarian is a 'health care provider' and, thus, eligible for an NPI. Any entity that insists veterinarians obtain an NPI are attempting to require veterinarians to obtain NPIs fraudulently (i.e., because the NPI Application/Update Form and its Internet equivalent require that the NPI applicant indicate that he/she/it meets the regulatory definition of 'health care provider' and a veterinarian does not)." Therefore, **pharmacists and pharmacies should not be asking veterinarians to provide an NPI.**

Urgent and Emergency Veterinary Compounding Guidance

After discussion with the Minnesota Veterinary Medical Association, and based on staff analysis and recommendations, the Board adopted the following position statement at its March 4, 2015 meeting.

"The Minnesota Board of Pharmacy will temporarily exercise enforcement discretion by not requiring a pharmacy to become licensed as a manufacturer when it compounds and distributes a limited supply of veterinary products that are needed in **urgent or emergency situations;** where the health of an animal is threatened, **or** where suffering or death of the animal is likely to result, from failure to treat."

The Board also issued the following guidance, pursuant to Minnesota Statutes §214.108, which states that a "health-related licensing board may offer guidance to current licensees about the application of laws and rules the board is empowered to enforce." **Note that this guidance will remain in effect only until the Board can promulgate appropriate rules related to this issue.**

1. Pharmacies licensed by the Board can already compound and dispense drugs, pursuant to a patient-specific prescription received in advance of the dispensing, provided that such compounding and dispensing is done according to Minnesota Statutes §151.253 and the applicable rules of the Board. (Note that only those pharmacies that have selected the nonsterile and/or sterile compounding licensing categories are allowed to compound drugs.) **Compounding done pursuant to a patient-specific prescription is not the subject of this guidance.**
2. The Board will exercise enforcement discretion and not take action against a pharmacy that, in good faith, provides a compounded drug to a veterinarian, at wholesale and without first receiving a patient-specific prescription, **only** when:
   a. The compounded drug is needed to treat animals in urgent or emergency situations; that is, where the health of an animal is threatened or where suffering or death of an animal is likely to result from failure to treat.
   b. Timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian.
   c. There is no Food and Drug Administration-approved, commercially manufactured drug that is suitable for treating the animal; or there is a documented shortage of such drug.
   d. The compounded drug is to be administered by a veterinarian or a bona fide employee of the veterinarian; or dispensed to a client of a veterinarian in an amount not to exceed what is necessary to treat an animal for a period of five days.
   e. The pharmacy is licensed by the Board as a drug wholesaler. (Except that a pharmacy may distribute compounded drugs as described in this guidance until June 1, 2015, without being licensed as a drug wholesaler.)
   f. The pharmacy has selected the sterile or nonsterile compounding licensing category.
   g. The pharmacy is appropriately registered by the United States DEA when providing compounded products that contain CS.

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.

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