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Minnesota Board of Pharmacy News

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Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions against **pharmacists** between the dates of July 17, 2014 and September 10, 2014.

Groehler, Scott A., License #114285. Mr Groehler petitioned the Board to have his license fully reinstated. He was disciplined by the Board in October 2013, after admitting that he was responsible for taking back drugs that had been erroneously sold to a patient and then redispensing them to the correct patient. He also admitted that he was responsible for a dispensing error that resulted in a child taking the incorrect drug for a one-month period of time. Upon being told by another pharmacist of the error, he did not notify either the parents of the patient or the prescriber. Mr Groehler provided proof to the Board that he had met all of the requirements for reinstatement of his license, including passing the Multistate Pharmacy Jurisprudence Examination®. Consequently, the Board adopted an order of full reinstatement at its September 10, 2014 meeting.

Keaveny, Deborah R., License #115503. Ms Keaveny admitted that, as pharmacist-in-charge (PIC), she allowed a pharmacy technician to work at a pharmacy without an active registration from January 1 through July 25, 2013. Consequently, at its September 10, 2014 meeting, the Board adopted a stipulation and consent order that reprimanded Ms Keaveny.

Narloch, Ross A., License #120159. During a five-month period of time in 2013, Dr Narloch was the PIC of a pharmacy in which a pharmacy technician was working without an active registration. Consequently, the Board adopted a stipulation and consent order at its July 30, 2014 meeting that reprimanded Dr Narloch.

Ngole, Mbong Peter, License #119494. Mr Ngole admitted that he was responsible for an error that involved the dispensing of an immediate release drug in place of the sustained release product that was prescribed. In certifying the prescription, Mr Ngole approved the override of four drug utilization review alerts, including one that recommended that a pediatric dosing reference be consulted. Consequently, the Board adopted a stipulation and consent order at its July 30, 2014 meeting that reprimanded Mr Ngole and required him to pay a civil penalty in the amount of $1,000.

Wachtl, Jason R., License #119029. Dr Wachtl petitioned the Board to have his license fully reinstated. He was disciplined by the Board in February 2011, after admitting that he diverted controlled substances (CS) from his employer for personal use, preparing fraudulent prescriptions to cover up the diversion. Dr Wachtl provided proof to the Board that he had met all of the requirements for reinstatement of his license. Consequently, the Board adopted an order of full reinstatement at its July 30, 2014 meeting.

The Board took the following disciplinary action against a **pharmacy** between the dates of July 17, 2014 and September 10, 2014.

Region's Hospital Pharmacy, License #200443. Representatives of this pharmacy admitted that a tech-check-tech program continued to be utilized for a period of time after the variance had expired. When a variance renewal request was submitted, it did not contain information that was supposed to be supplied as a condition of having the variance renewed. Consequently, the Board adopted a stipulation and consent order at its July 30, 2014 meeting that reprimanded the pharmacy and required payment of a civil penalty in the amount of $5,000.

The Board took the following disciplinary action against a drug **wholesaler** between the dates of July 17, 2014 and September 10, 2014.

Midwest Vet Supply, Inc, License #300227. Representatives of this wholesaler admitted that veterinarians sent it orders for compounded prescription drugs. Midwest Vet transcribed these orders by entering them into an electronic database interface (EDI). After entering the orders into the EDI, Midwest Vet transmitted the orders to a business located in New Jersey that is licensed by the Board only as a nonresidential pharmacy and not as a drug wholesaler (New Jersey Pharmacy). The New Jersey Pharmacy then sold the compounded prescription drugs to the veterinarians without first receiving patient-specific prescriptions, making the sales wholesale transactions, even though it was not licensed as a wholesaler. Midwest Vet received payment from the New Jersey Pharmacy for its participation in these illegal wholesale transactions. Consequently, the Board adopted a stipulation and consent order at its July 30, 2014 meeting that reprimanded Midwest Vet and required payment of a civil penalty in the amount of $25,000.

The Board took the following disciplinary actions against **technicians** between the dates of July 17, 2014 and September 10, 2014.

Genis-Salinas, Gisela, Registration #725037. Ms Genis-Salinas admitted that she worked as a pharmacy technician from January 1 through November 25, 2013, without an active registration. Consequently, the Board adopted a stipulation and consent order at its July 30, 2014 meeting that reprimanded Ms Genis-Salinas and required payment of a civil penalty in the amount of $150.

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DEA Reschedules Hydrocodone Combination Products as Schedule II

Drug Enforcement Administration (DEA) has published its final rule rescheduling hydrocodone combination products from Schedule III to Schedule II in the *Federal Register.* The change imposes Schedule II regulatory controls and sanctions on anyone handling hydrocodone combination products, effective October 6, 2014. DEA first published the proposed rules in March 2014 in response to a Food and Drug Administration (FDA) recommendation. DEA received almost 600 public comments regarding the proposed rules after they were published, with a small majority of the commenters supporting the change, DEA notes in a press release, which is available at *www.justice.gov/dea/divisions/hq/2014/hq082114.shtml.*

The announcement is available on the *Federal Register* website at *https://federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule.*

The mL-Only Standard for Liquid Dosing Gathers Steam

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. *E-mail: ismpinfo@ismp.org.*

ISMP first reported on the confusion of teaspoonfuls and milliliters (mL) in its newsletter in 2000, and in 2009, issued a call for practitioners to move to sole use of the metric system for measuring over-the-counter and prescription oral liquid doses, but mix-ups have continued to result in the serious injury of children and adults. Use of the metric system alone when prescribing, dispensing, and administering medications would prevent mix-ups because there would only be one method used to communicate and measure doses.

The health care industry is beginning to acknowledge the risk of confusion when using non-metric measurements, especially with oral liquid medications. The National Council for Prescription Drug Programs (NCPDP) just released a white paper entitled *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* which is available at *www.ismp.org/sc?id=337.* The white paper supports mL as the standard unit of liquid measure used on prescription container labels for oral liquid medications. It also calls for dosing devices with numeric graduations, and for units that correspond to the container labeling to be easily and universally available, such as including a device each time oral liquid prescription medications are dispensed. NCPDP also reiterates that dose amounts should always use leading zeroes before the decimal point for amounts less than one, and should not use trailing zeroes after a decimal point on labels for oral liquid medications.

The white paper comes as welcome news and is well-aligned with the *ISMP 2014-15 Targeted Medication Safety Best Practices for Hospitals,* Best Practice 5, which calls for organizations to use oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale. The white paper also comes at a time when the Centers for Disease Control and Prevention, ISMP, the Consumer Healthcare Products Association, the United States FDA, the US Metric Association, and the American Academy of Pediatrics have initiatives in place that will help guide health care organizations to commit to metric measurements.

ISMP recommends the following actions to help prevent errors:

- Use only metric units, not teaspoon or other non-metric measurements, for all patient instructions, including those listed in prescribing and pharmacy computer systems. This should cover directions incorporated into computer system mnemonics, speed codes, or any defaults used to generate prescriptions and prescription labels.
- Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters.
- Coach patients on how to use and clean measuring devices; use the "teach back" approach and ask patients or caregivers to demonstrate their understanding.

DEA Classifies Tramadol a Controlled Substance

Under a final rule published in the *Federal Register*, the pain reliever tramadol is now classified as a Schedule IV controlled substance. As of August 18, 2014, DEA requires manufacturers to print the "C-IV" designation on all labels that contain 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol (tramadol), including its salts, isomers, and salts of isomers. The agency notes that every "DEA registrant who possesses any quantity of tramadol on the effective date of this final rule must take an inventory of all stocks of tramadol on hand as of August 18, 2014, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11 (a) and (d)." In addition, all "prescriptions for tramadol

or products containing tramadol must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of August 18, 2014."

The announcement is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/07/02/2014-15548/schedules-of-controlled-substances-placement-of-tramadol-into-schedule-iv*.

FDA Lowers Recommended Starting Dose for Lunesta Due to Risk of Morning Impairment

FDA has lowered the recommended starting dose of the sleep drug Lunesta® (eszopiclone) from 2 mg to 1 mg. Patients who are currently taking 2 mg and 3 mg doses of eszopiclone should contact their health care provider to ask for instructions on how to continue to take their medication safely at a dose that is best for them, FDA advises. The dose change came after findings from a study of 91 healthy adults found that the medication was associated with impairment to driving skills, memory, and coordination for as long as 11 hours after the drug is taken, FDA notes.

More information is available in an FDA news release at *www.fda.gov/newsevents/newsroom/pressannouncements/ucm397453.htm*.

Lidocaine Should Not Be Used to Treat Teething Pain in Children, FDA Warns

FDA is recommending that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain, and is now requiring a new boxed warning to be added to the drug label to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death, indicates FDA in a June 2014 Safety Announcement. FDA advises health care providers not to prescribe or recommend this product for teething pain. FDA is also requiring the "Warnings" and "Dosage and Administration" sections of the drug label to describe the risk of severe adverse events and to include additional instructions for dosing when the drug is prescribed for approved uses.

In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children who were either given lidocaine for treatment of mouth pain, or who accidentally ingested the medication.

More information is available in the safety announcement on FDA's website at *www.fda.gov/Drugs/DrugSafety/ucm402240.htm*.

FDA Reiterates Warning Against Using NuVision Pharmacy Products

Health care providers should not use or distribute compounded drugs marketed as sterile produced by Downing Labs, LLC, of Dallas, TX, also known as NuVision Pharmacy, warns FDA. Inspection results issued on July 16, 2014, indicate that FDA observed unsanitary conditions resulting in a lack of sterility assurance of sterile drug products produced by the company, which may put patients at risk, FDA notes in the safety announcement. "The inspection revealed sterility failures in 19 lots of drug products intended to be sterile, endotoxin failures in three lots of drug products, and inadequate or no investigation of these failures," states FDA in the announcement.

In 2013, the agency issued several similar warnings following NuVision's refusal to recall all sterile products. In April 2013, NuVision recalled methylcobalamin injection and lyophilized injection products, citing concerns about sterility in the wake of adverse event reports. Health care providers and consumers may report adverse events or quality problems associated with NuVision products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Additional information is available in the safety announcement, available on FDA's website at *www.fda.gov/Drugs/DrugSafety/ucm405940.htm*.

JCPP Releases New Patient-Care Document to Promote Consistency

The Joint Commission of Pharmacy Practitioners (JCPP) has released a resource document aimed at promoting consistency in the pharmacists' process of patient care service delivery. "Pharmacists' Patient Care Process" was developed by examining key source documents on pharmaceutical care and medication therapy management. The document describes the process in five parts: collect, assess, plan, implement, and follow-up.

JCPP brings together the chief executive officers and elected officers of national pharmacy associations, including the National Association of Boards of Pharmacy®, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice.

The document can be downloaded online at *www.pharmacist.com/sites/default/files/JCPP_Pharmacists_Patient_Care_Process.pdf*.

CPE Credit Offered for FDA Course on Misleading Prescription Drug Promotion

To raise awareness about the risks associated with false or misleading prescription medication marketing, FDA, in partnership with Medscape, is offering an online, one-hour continuing education course through its Bad Ad Program. Pharmacists may receive continuing pharmacy education (CPE) credit by taking this course. Learning objectives, faculty information, and other information is available on the course's website at *www.sigmatech.com/BadAd*. There is no registration fee for the course. Upon completion, pharmacists will receive one Accreditation Council for Pharmacy Education-accredited CPE hour (0.1 continuing education unit).

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Jacobson, Katie M., Registration #719760. Ms Jacobson admitted that she diverted hydrocodone-containing products from the pharmacy at which she worked. The diversion was for her personal use. She subsequently pleaded guilty to felony, fifth-degree possession of a CS. Consequently, the Board issued a stipulation and consent order for voluntary surrender of registration at its July 30, 2014 meeting.

Monnens, Caroline M., Registration #704844. Ms Monnens admitted that she diverted hydrocodone-containing products from the pharmacy at which she worked. The diversion was for her personal use. Consequently, the Board issued a stipulation and consent order for voluntary surrender of registration at its July 30, 2014 meeting.

2014 Legislation Update: 'Steve's Law'

During its 2014 Minnesota State Legislative Session, the Minnesota State Legislature passed a bill that is referred to as "Steve's Law." Named after Steve Rummler, who died of a heroin overdose in July 2011, after years of struggling with an addiction to prescribed opioid pain relievers, this new law:

- Provides some immunity from prosecution to individuals who, acting in good faith, seek medical assistance for another person who is experiencing a drug-related overdose;
- Allows properly trained personnel of basic life-support ambulances to administer opiate antagonists;
- Allows physicians, advanced practice registered nurses (APRNs), and physician assistants (PAs) to authorize the following individuals to administer opiate antagonists: emergency medical responders, law enforcement officers, and staff of community-based health, disease prevention, or social service programs;
- Allows an individual who is not a licensed health care professional to possess and administer an opiate antagonist to another individual, as long as the antagonist has been prescribed, dispensed, or distributed by a health care professional who is licensed to prescribe;
- Provides civil and criminal immunity to individuals who administer opiate antagonists as described in the previous bullet point; and
- States that a health care professional who is licensed to prescribe may "directly or by standing order prescribe, dispense, distribute, or administer an opiate antagonist to a person without being subject to civil liability or criminal prosecution for the act."

Steve's Law provides opportunities for pharmacists to get involved in efforts that can save the lives of individuals who are addicted to prescription drugs. The Board has been contacted by individuals who have asked if there have been any discussions to remove prescribing restrictions from naloxone to allow pharmacists to dispense under a restricted protocol. As explained in a FAQs document that is available on the Board's website:

> Prescribing restrictions don't have to be removed in order for pharmacists to dispense naloxone under a protocol. MN Stats. Sec. 151.01, subd. 27 allows pharmacists to participate in the initiation, management, modification and discontinuation of drug therapy per protocol or collaborative practice agreement with a physician, advanced practice registered nurse or physician assistant. MN Stats. Sec. 151.37 allows a practitioner to "prescribe a legend drug, without reference to a specific patient, by directing a . . . pharmacist according to section 151.01, subdivision 27, to adhere to a particular practice guideline or protocol when treating patients whose condition falls within such guideline or protocol, and when such guideline or protocol specifies the circumstances under which the legend drug is to be prescribed and administered."
>
> So, a MD, PA or APRN can enter into a protocol with one or more pharmacists that allow the pharmacists to prepare a legally valid prescription for naloxone. In this case, the practitioner is still considered to be the prescriber of record . . . Since pharmacists can administer drugs in emergency situations, the pharmacist could even administer the naloxone to a patient who was experiencing an overdose.

Pharmacists are encouraged to obtain additional information about Steve's Law on the Board's website at: 2014 Naloxone Legislation FAQ.

DEA Rules Concerning Collection of CS

Drug Enforcement Administration (DEA) recently issued new rules that will allow pharmacies, wholesalers, manufacturers, and certain other DEA registrants to "collect pharmaceutical controlled substances from ultimate users by voluntarily administering mail-back programs and maintaining collection receptacles. In addition, the regulations allow authorized hospitals/clinics and retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities."

However, Minnesota statutes **do not** currently allow pharmacies, drug manufacturers, hospitals, clinics, drug treatment programs, or any other health care facility to accept drugs from "ultimate users" for the purpose of having them disposed of as waste. This is true for any drug, not just CS. Several years ago, the Minnesota State Legislature passed legislation that specifies the individuals and facilities that are allowed to possess prescription drugs for the purpose of disposing of them as pharmaceutical waste. Pharmacies, drug treatment programs, clinics, hospitals, drug manufacturers, and other health facilities are not listed as being entities that can collect pharmaceutical waste.

Drug wholesalers that are reverse distributors can collect pharmaceutical waste for the purpose of disposal. Some reverse distributors operate mail-in programs. Pharmacies and other health care facilities can provide mail-in envelopes/packages to consumers provided that the drugs are mailed back to the reverse distributor. The drugs cannot be mailed back to the pharmacy or other health care facility. Pharmacies and other health care facilities cannot maintain collection receptacles at this time.

You may want to refer patients and other consumers to the following page of the Minnesota Pollution Control Agency (MPCA) website: *www.pca.state.mn.us/index.php/living-green/living-green-citizen/household-hazardous-waste/disposing-of-unwanted-medications.html.* This page provides information for consumers about the proper disposal of pharmaceutical waste.

The Board supports the collection of pharmaceutical waste by pharmacies, and Board staff is in the process of working with the MPCA on legislation that the Board will introduce during the 2015 legislative session. It will be drafted to allow pharmacies and other health care facilities to maintain collection receptacles as long as DEA rules are followed and as long as certain other requirements are met.

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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