October 2014

Oklahoma State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

2920 N Lincoln Blvd, Suite A • Oklahoma City, OK 73105-3488

From the Inspector's Desk

- **14.18. Out-of-State APRNs:** Oklahoma pharmacies may fill prescriptions written by out-of-state advance practice registered nurses (APRNs) **only if** the APRN is also licensed in Oklahoma and is currently working with and supervised by an Oklahoma-licensed physician at the time the prescription is written. Oklahoma laws governing APRN prescribing limitations will apply regardless of where the prescription is written.
- **14.19. E-Prescribing:** E-prescribing of medications is allowed, including Schedule II-V, as long as both the pharmacy **and** the prescriber's software are properly certified. Check with your software company to see if your software is certified. E-prescribed controlled prescriptions shall be stored electronically per Drug Enforcement Administration (DEA) requirements, and must be maintained in a readily retrievable format for five years. The following links have a partial list of approved pharmacies and prescribers:
  - ◊ *http://surescripts.com/network-connections/mns/connected-pharmacies*
  - ◊ *http://surescripts.com/network-connections/mns/prescriber-software*

  Faxed prescriptions are not considered the same as e-prescribed prescriptions. Faxed prescriptions must originate from the practitioner's office. If they are faxed from the hospice or nursing home, then the original must be obtained prior to dispensing the medication. Faxed prescriptions for a controlled substance (CS) must bear the manual signature of the prescriber. They cannot bear a stamped or a computer-generated signature. All computer-generated controlled prescriptions, whether printed out or faxed, must be manually signed per Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) and DEA regulations. Non-controlled prescriptions do not have to bear the manual signature of the prescriber. Faxed prescriptions may also be stored electronically in a readily retrievable format for five years.

  E-mailed prescriptions are not considered the same as e-prescribed prescriptions and are **not** permitted. This is not a secure method of transmission.
- **14.20. Hydrocodone Becomes Schedule II:** All hydrocodone-containing products become classified as a Schedule II CS, effective October 6, 2014. Even though they have been a CS, all hydrocodone products will need to be inventoried on October 6, 2014, and a copy of that inventory will need to be maintained in a readily retrievable file. Please **do not** mail your inventory to the Oklahoma State Board of Pharmacy.

  Mid-level practitioners will not be able to prescribe hydrocodone combination products after October 6, 2014. Prescriptions written prior to October 6, 2014, by mid-level practitioners will still be valid for a period of six months (through April 8, 2014). More detailed information may be found on the Board's website at *www.ok.gov/OSBP/documents/Hydrocodone_Reschedule_20140828.pdf.*
- **14.21. Pharmacists-in-Charge:** Pharmacists-in-charge (PICs) are responsible for everything that occurs in their pharmacy. They must be aware of the quantities of CS that are being ordered into the pharmacy compared to what is being dispensed. They must be competent in their field of pharmacy, whether that is hospice, compounding, nursing home, or hospital. If the pharmacy is owned by another entity or, particularly, a non-pharmacist, a PIC must not let the owner make decisions that are contrary to the law. If business practices are contrary to the Oklahoma Pharmacy Act, then violations must be reported to the Board. If illegal activities are permitted to occur, the pharmacist's license may be at risk, even if the pharmacist is not directly involved. This may include a technician stealing large quantities of CS, a pharmacist failing to properly supervise employees, or a business owner committing insurance fraud.
- **14.22. DEA Take-Back Rule Change:** Effective October 9, 2014, DEA will allow registrants to take back medications, including CS, from "ultimate users" for destruction. An "ultimate user" is a patient or family member who has lawfully obtained a medication by prescription. Registrants will have to modify their DEA registration online to become an "authorized collector." Collectors may maintain collection receptacles inside their registered location or operate a mail-back program, but only law enforcement is authorized to conduct take-back events.

  At this time, Oklahoma law prohibits pharmacies from receiving CS from ultimate users. The Board will notify you if the law is changed. You may direct citizens to the nearest take-back box at *https://portal.obn.ok.gov/takeback/default.aspx.*

Continued on page 4

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).

Continued from page 1

The take-back boxes may not be used for liquids, syringes, or inhalers. Registrants may not use the take-back program to destroy or dispose of their own inventory. All controlled medications must be documented and returned through a reverse distributor or wholesaler.

- **14.23. PMP Shares with Neighboring States:** Beginning November 1, 2014, the Oklahoma Bureau of Narcotics (OBN) will have the ability to share information with neighboring states as part of OBN's ongoing initiative to enhance Prescription Monitoring Program (PMP) capabilities. Data sharing will be limited to the terms and conditions established by each state. These states include Kansas, Arkansas, Texas, New Mexico, and Colorado.

14.24. OHCA Limits Short-Acting Opiates

The Oklahoma Health Care Authority (OHCA) is focused on decreasing opioid abuse and diversion. OHCA will implement a claims edit that will block payment for short-acting products in quantities greater than four per day for chronic use. In effect, claims for quantities of short-acting opioid products greater than 120 units over a 30-day time period will be rejected.

Both the Board and the OBNDD Control agree that a prescription written for a greater quantity could be split – filling the maximum under SoonerCare (120 units) and the remainder for cash – as long as Schedule II and hydrocodone products are completed in one transaction on the same day. OHCA recommends submitting the claims as 120 units per 30 days in order to avoid the need for prior authorization or an override. The remaining quantity should be dealt with according to the individual pharmacy's policies and procedures.

More information about the edit will be provided by OHCA prior to implementation. Questions may be directed to pharmacy @okhca.org or to the Pharmacy Help Desk at 1-800/522-0114, option 4.

Disciplinary Actions

For more information, you may view hearing minutes at *www.pharmacy.ok.gov.*

14.25. June 12, 2014 Board Hearing

OK Compounding, LLC, #2-6161 – Case No. 1268: Admitted to guilt on one count and neither admits nor denies guilt on the remaining 6,535 counts including, but not limited to, employee training, record keeping, proper billing for services, properly licensed staff, unlicensed interstate sales, failing to perform and document an adequate final check of preparations prior to their release from the pharmacy, and failing to have available written policies and procedures for all steps in the compounding of preparations. **Placed on probation for three years until April 16, 2017. $520,200 fine. Must cease business operations and fill no prescriptions for five full days between June 12, 2014 and July 21, 2014.**

Muscogee (Creek) Nation DME, #14-S-3878 – Case No. 1275: Admitted to guilt on three counts including failing to register with the Board as a medical gas supplier before conducting interstate and/or intrastate transactions in Oklahoma. **Placed on probation for one year until June 12, 2015. $1,000 fine.**

Mercy Hospital Oklahoma City, #1-5963 – Case No. 1279: Found guilty on 31 counts including failing to furnish the necessary preceptor(s) under whose supervision an intern will be allowed to perform intern duties; failing to have a director of pharmacy who is responsible for all activities of the hospital pharmacy; and failing to have a pharmacy manager who is responsible for all aspects of the operation related to the practice of pharmacy. **$62,000 fine.**

Santosh Jeremy John, DPh, #13118 – Case No. 1280: Found guilty on 32 counts including failing to furnish the necessary preceptor(s) under whose supervision an intern will be allowed to perform intern duties; failing, as pharmacy manager, to be responsible for all aspects of the operation related to the practice of pharmacy; failing, as director of pharmacy, to be responsible for all activities of the hospital pharmacy; and failing to maintain adequate staffing levels of pharmacists. **Respondent is ordered to pay a fine of $3,000, and attend a preceptor conference and a one-day (eight-hour) law seminar during the calendar year 2014.**

Amy Bennett, Technician #13636 – Case No. 1281: Found guilty on four counts including possession of a controlled dangerous substance (CDS) without a valid prescription and abusing alcohol or drugs, using an illegal CDS substance, and/or testing positive for such substance or its metabolite. **Revoked.**

Brittany LeAnn Coley, Technician #17628 – Case No. 1282: Admitted to guilt on three counts including theft while working as a registrant. **Revoked.**

Gabriella Martinez, Technician #17482 – Case No. 1283: Found guilty on three counts including possession of a CDS without a valid prescription and theft while working as a registrant. **Revoked.**

Quantum Medical, Inc, #3-4367 – Case No. 1285: Admitted to guilt on 28 counts including failing to meet United States Pharmacopeia (USP) Compounding Standards and Board rules for sterile compounding; failing to establish and maintain effective controls against diversion; failing to supervise employees as they relate to the practice of pharmacy; allowing someone other than a pharmacist to unlock the pharmacy area; allowing prescription medications to be left outside the prescription area when the pharmacist is not in attendance; failing to have an area designated for the preparation of sterile therapeutic preparations; failing to have a sink with hot and cold running water that is convenient to the compounding area; allowing a person to have access to the parenteral pharmacy in the absence of an Oklahoma-registered pharmacist; failing to have a documented, ongoing quality assurance program; failing to ensure that all compounders who compound pharmaceuticals meet all requirements for training, testing, and education; failing to have available for inspection completed documentation of pharmacist-supervised training and testing in product preparation of pharmacy technicians participating in the preparation of compounded products; preparing an inordinate amount of products in anticipation of a prescription prior to receiving a valid prescription; failing to properly label and store hazardous drugs; failing to require that all staff wear personnel protective equipment (PPE) while working with hazardous drugs; failing to make the required facility improvements within the time required; failing to require a technician to have received a pharmacy technician permit before performing any of the duties of pharmacy technicians; failing to document training of a currently permitted technician within 10 days of hire; and placing drugs with a home care agency, pursuant to agreement, that are

Continued on page 5

Continued from page 4

not allowed by Board rules. **Parenteral (sterile compounding) permit is suspended. Must provide sterile and nonsterile compounding policies and procedures manual to Board for approval prior to being allowed to compound. $7,500 fine.**

James Casebeer, DPh, #10740 – Case No. 1286: Admitted to guilt on 32 counts including failing to meet USP Compounding Standards and Board rules for sterile compounding; failing to establish and maintain effective controls against diversion; failing to supervise employees as they relate to the practice of pharmacy; allowing someone other than a pharmacist to unlock the pharmacy area; allowing prescription medications to be left outside the prescription area when the pharmacist is not in attendance; allowing a person to have access to the parenteral pharmacy in the absence of an Oklahoma-registered pharmacist; failing to have a documented, ongoing quality assurance program; failing to have available for inspection completed documentation of pharmacist-supervised training and testing in product preparation of pharmacy technicians participating in the preparation of compounded products; preparing an inordinate amount of products in anticipation of a prescription prior to receiving a valid prescription; failing to properly label and store hazardous drugs; failing to require that all staff wear PPE while working with hazardous drugs; failing to make the required facility improvements within the time required; failing to document training of a currently permitted technician within 10 days of hire; and placing drugs with a home care agency, pursuant to agreement, that are not allowed by Board rules. **Placed on probation for five years until June 12, 2019. $5,000 fine. Must successfully complete both sterile and nonsterile compounding education approved by the Board, and show that his resumed compounding would not put the public at risk before doing either sterile or nonsterile compounding. Shall attend a one-day (eight-hour) law seminar in addition to the required 15 hours of continuing education (CE) during the calendar years of 2014 and 2015. All CE required for license renewal shall be live during the five years of probation.**

Impaired Pharmacist, DPh, #15347 – Case No. 1288: Admitted to guilt on six counts including possession of a CDS without a valid prescription; theft while practicing pharmacy; and practicing pharmacy without reasonable skill and safety by reason of illness, use and/or abuse of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. **Placed on probation for 10 years until June 12, 2024. $3,000 fine. Shall attend a one-day (eight-hour) law seminar in addition to the required 15 hours of CE during the calendar years of 2014 and 2015. All CE required for renewal for the years 2015 through 2024 shall be live. Respondent must enter into and abide by a 10-year contract with Oklahoma Pharmacists Helping Pharmacists (OPHP).**

14.26. August 6, 2014 Board Hearing

Impaired Pharmacist, DPh, #8217 – Case No. 1287: Agreed to guilt on three counts including conducting himself in a manner likely to lower public esteem for the profession of pharmacy and exercising conduct and habits inconsistent with the rules of professional conduct. **Current probation ending August 21, 2015, is extended three years until August 21, 2018. $3,000 fine. Must enter into five-year contract with OPHP and attend a one-day (eight-hour) law seminar in addition to the required 15 hours of CE during the calendar years of 2014 and 2015. All CE required for renewal of license while on probation shall be live.**

Jennifer Hooks, Technician #18521 – Case No. 1290: Admitted to guilt on four counts including possession of a CDS without a valid prescription and abusing alcohol or drugs, using an illegal CDS substance, and/or testing positive for such substance or its metabolite. **Revoked.**

Jessica Mitchell, Technician #18413 – Case No. 1291: Found guilty on four counts including possession of a CDS without a valid prescription and theft while working as a registrant. **Revoked.**

SMC Plaza Pharmacy, #1-6348 – Case No. 1292: Neither admits nor denies guilt on four counts including failing to establish and maintain effective controls against the diversion of prescription drugs. **$12,000 fine.**

Calendar Notes

The Board will meet on **October 1, 2014** and **November 19, 2014.** The Board will be closed Tuesday, **November 11,** for Veterans Day; Thursday and Friday, **November 27 and 28,** for Thanksgiving; Wednesday and Thursday, **December 24 and 25,** for Christmas; and Thursday, **January 1, 2015,** for New Year's Day. Future Board dates will be available at *www.pharmacy.ok.gov* and will be noted in the January *Newsletter.*

Change of Address or Employment?

Please be diligent in keeping your information up to date and if possible, remind your coworkers and employees. This continues to be an ongoing problem, and failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are also accepted as official notification.

Special Notice About the Newsletter

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. OPHP is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574, ext. 5773. All calls are confidential.

"This publication is issued by the Oklahoma State Board of Pharmacy as authorized by Title 59 O.S. 353.7. Copies have not been printed but are available through the agency website."

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