July 2017

Oklahoma State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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From the Inspector's Desk

- **17.18. Non-CDS Invoices:** Non-controlled dangerous substance (CDS) invoices may now be stored electronically. Per Oklahoma Administrative Code (OAC) **535:15-3-18. Pharmacy prescription drug purchase records:** "All prescription purchases (eg, invoices) and inventory records shall be maintained and be readily retrievable for a period of at least 2 years." Invoices for non-controlled drugs may be maintained electronically.
- **17.19. Inspection Reports:** After a compliance officer has been in the pharmacy to conduct an inspection, you should not just immediately file away the inspection report. You should keep it visible for all staff to read and until all corrections have been addressed.
- **17.20. Media Fill Testing United States Pharmacopeia (USP) <797>:** Incubation temperature(s) are 20º-25ºC (68º-77ºF) or 30º-35ºC (86º-95º) for a minimum of 14 days. If two temperatures are used for incubation of media fill samples, then these filled containers should be incubated for at least seven days at each temperature.
- **17.21. Gloved Fingertip Sampling USP <797>:** Incubation temperature is 30º-35ºC (86º-95ºF) for 48 to 72 hours.

Disciplinary Actions

For more information, you may view hearing minutes at *http://ok.gov/pharmacy/Board/Minutes/index.html.*

17.22. March 29, 2017 Board Hearing

Impaired Intern #7452 – Case No. 1104: Removed requirements that he shall have no access to CDS and that he shall obtain Board permission to take the North American Pharmacist Licensure Examination®. Must continue to abide by his 10-year contract with Oklahoma Pharmacists Helping Pharmacists (OPHP).

Impaired Pharmacist #14268 – Case No. 1324: Board approved reinstatement of license. Upon reinstatement, license will be placed on probation until December 15, 2025. **Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of live continuing education (CE) in the calendar years 2017 and 2018. All CE required to renew her license during probation must be live.**

Noble Pharmacy, #7-2595 – Case No. 1443: Admitted guilt on 217 counts including failing to comply with all applicable federal, state, and local law and regulation concerning pharmacy; failing to have available, follow, and retain written policies and procedures for all steps in the compounding of preparations; failing to routinely inspect, calibrate as necessary, or check to ensure proper performance of equipment used in the compounding of drug products; failing to assign every compounded preparation an appropriate beyond-use date (BUD); failing to label any excess compounded preparation; failing to train every individual who prepares compounded preparations; failing to administer a written test on material referenced in OAC 535:15-10-3 and to require that this test be passed by staff preparing compounded preparations upon initial hire or prior to assignment to compound preparations; failing to test annually every individual involved in compounding preparations; failing to train and evaluate staff by using media-fill challenge tests to evaluate sterile technique; failing initially and at least annually to train and evaluate staff using glove fingertip sampling processes; failing to require personnel to follow proper procedures for personnel cleansing and garbing prior to compounding; failing to handle and store drug product containers and closures in a manner to prevent contamination; failing to establish procedures for sterilization of all products prepared with any nonsterile ingredients; failing to comply with all aspects of USP compounding standards; failing to install a pressure gauge or velocity meter to monitor the pressure differential or airflow between the clean room and the general environment outside the compounding area; failing to include on the prescription label for a compounded prescription BUD and storage; and failure to remove all outdated prescription drugs from the active inventory area upon expiration. **$32,550 fine and placed on probation for five years until March 29, 2022.**

Gary Todd, DPh #9812 – Case No. 1444: Admitted guilt on 12 counts including failing to be familiar with all details of USP compounding standards; failing to ensure preparations are of acceptable strength, quality, and purity; failing to assign the proper BUDs to compounded sterile and nonsterile preparations; failing to ensure that all compounders who compound

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WHO Launches Global Patient Safety Challenge on Medication Safety

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

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

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

Continuous Quality Improvement and Patient Safety Organizations

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

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

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

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

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

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

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

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

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

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

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

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

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

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

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

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

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

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

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

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

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

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

CPE Training on Older Adult Fall Prevention Available Online

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

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

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Combat Methamphetamine Epidemic Act," pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

FDA Presents Series of CE Webinars for Students and Clinicians

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

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pharmaceuticals meet all requirements for training, testing, and education; and failing to have available, follow, and retain written policies and procedures for all steps in the compounding of preparations. **$1,800 fine and placed on probation for five years until March 29, 2022. Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of live CE in the calendar year 2017.**

Kim Nguyen, DPh #15778 – Case No. 1445: Admitted guilt on nine counts including failing to be familiar with all aspects of USP compounding standards; failing to ensure preparations are of acceptable strength, quality, and purity; failing to ensure appropriate stability evaluation is performed; failure to ensure proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice; and failing to be proficient in compounding. **$900 fine and placed on probation for two years until March 29, 2019. Respondent shall complete 15 hours of Oklahoma State Board of Pharmacy-approved USP <797> compounding training before September 29, 2017. Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of live CE in the calendar year 2017.**

Apotheke, #2-7630 – Case No. 1449: Admitted guilt on 53 counts including failing to keep separate records of sales on file and available for inspection; failing to verify all critical processes; compounding a drug preparation that is commercially available in the marketplace or that is essentially a copy of an available Food and Drug Administration (FDA)-approved drug product; failing to comply with all aspects of USP compounding standards; failing to administer a written test on material referenced in OAC 535:15-10-3 and to require that this test be passed by staff preparing compounded preparations upon initial hire or prior to assignment to compound preparations; compounding a prescription when computer information and the hard copy of the prescription do not indicate that the prescription is to be compounded; misfilling a prescription; giving or selling compounded preparations for resale by prescribers or other persons; failing to oppose any arrangements inimical to public health; and failing to include all required information on the filled prescription label. **Respondent shall sell and transfer title to the pharmacy on or before September 29, 2017.**

Caleb Meacham, DPh #14927 – Case No. 1450: Admitted guilt on 53 counts including failing to keep separate records of sales on file and available for inspection; failing to verify all critical processes; compounding a drug preparation that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product; failing to comply with all aspects of USP compounding standards; failing to administer a written test on material referenced in OAC 535:15-10-3 and to require that this test be passed by staff preparing compounded preparations upon initial hire or prior to assignment to compound preparations; compounding a prescription when computer information and the hard copy of the prescription do not indicate that the prescription is to be compounded; misfilling a prescription; giving or selling compounded preparations for resale by prescribers or other persons; failing to oppose any arrangements inimical to public health; and failing to include all required information on the filled prescription label. **$15,000 fine and license suspended from May 1 to May 31, 2017. On June 1, 2017, the suspension was lifted and license placed on probation for five years until June 1, 2022. Respondent shall not work as a pharmacist-in-charge while on probation. As of June 1, 2017, respondent shall not do either sterile or nonsterile compounding until June 1, 2018. After June 1, 2018, respondent can request Board staff approval to compound. Respondent shall take and pass the Multistate Pharmacy Jurisprudence Examination® before July 25, 2017. Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of live CE in the calendar years 2017-2022. Respondent shall not have an ownership interest in either a pharmacy or an outsourcing facility while he is on probation.**

Amerita, #2-7746 – Case No. 1453: Admitted guilt on 18 counts and pled nolo contendere to six counts including failure to comply with all aspects of USP compounding standards; failing to have available written policies and procedures for all steps in the compounding of preparations; failure to establish procedures for yearly testing the techniques of pharmacists using simulated aseptic procedures; failing to routinely inspect, calibrate as necessary, and check to ensure proper performance of equipment used in the compounding of drug products; failing to train all individuals who compound sterile preparations; failure to comply with all applicable federal, state, and local law and regulation concerning pharmacy; failing to require personnel to follow proper procedures for personnel cleansing and garbing prior to compounding; failing to do routine disinfection and air quality testing of the direct compounding environment; failure to install a pressure gauge or velocity meter to monitor the pressure differential or airflow between the clean room and the general environment outside the compounding area; failing to establish and maintain effective controls to prevent prescription errors; failing to ensure that only authorized personnel are in the immediate vicinity of the drug compounding operation; failing to require personnel to follow proper procedures in the cleaning and disinfection of sterile compounding areas; failing to have compounding equipment that is of suitable composition; failing to ensure the proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice; failing to have equipment used in the compounding of drug preparations that is of appropriate design and capacity; and failure to have a pharmacy manager who is responsible for the development and/or implementation of a pharmacy technician training program. **$36,000 fine and placed on probation for five years until March 29, 2022. All pharmacists and pharmacy technicians currently employed by or hired by respondent before March 29, 2017, shall be trained in sterile compounding by a Board-approved entity by September 29, 2017. Every three months of the first year and every six months of the remaining four years that respondent is on probation, all of respondent's employees doing sterile compounding shall pass fingertip glove tests, media fill tests, and competency tests. At all times during the compounding process, a pharmacist must be garbed and present inside the sterile compounding room. All sterile compounding lab areas shall be ISO-certified biannually.**

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Cindy Leonard, DPh #15141 – Case No. 1454: Admitted guilt on four counts including failing to comply with all aspects of USP compounding standards; failing to supervise all employees as they relate to the practice of pharmacy; failing to verify all critical processes; and failing to have available written policies and procedures for all steps in the compounding of preparations. **$2,000 fine and placed on probation for three years until March 29, 2020. Respondent shall complete 15 hours of Board-approved USP <797> compounding training before September 29, 2017. Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of live CE in the calendar year 2017.**

Pascaline Nwokoma, DPh #16869 – Case No. 1455: Admitted to guilt on four counts including failing to establish and maintain effective controls against prescription errors or misfills; receiving a warning notice; and failing to conduct business at all times in conformity with all federal, state, and municipal laws. **$2,000 fine and placed on probation for three years until March 29, 2020. Respondent shall complete 15 hours of Board-approved USP <797> compounding training before September 29, 2017. Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of live CE in the calendar year 2017.**

Kyala Gross, Technician #21425 – Case No. 1456: Admitted guilt on three counts including committing theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

Samantha Jo McCracken, Technician #21549 – Case No. 1457: Found guilty on three counts including committing theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

Misty D. Stevens, Technician #20051 – Case No. 1458: Neither admits nor denies guilt on five counts including committing theft while working as a registrant; possession of a CDS without a valid prescription; and impersonating a pharmacist. **Revoked.**

Stacy McCage, Technician #17955 – Case No. 1459: Admitted guilt on three counts including committing theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

Thomas Hill, DPh #11099 – Case No. 1460: Admitted guilt on three counts including making or filing a report or record that he knew or should have known to be false and making a false representation in procuring or attempting to procure a renewal. **$1,000 fine and placed on probation for one year until March 29, 2018.**

Suzette Chapple, DPh #12434 – Case No. 1461: Admitted guilt on four counts including misfilling a prescription; not attempting to resolve a possible prescription error or situation of potential harm to the patient; and receiving two warning notices. **$2,000 fine and placed on probation for three years until March 29, 2020. Respondent shall complete 15 hours of Board-approved USP <797> compounding training before September 29, 2017. Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of live CE in the calendar year 2017.**

Southern Plains Vet Supply – Application for Pharmacy License Show Cause Hearing: Applicant furnished to the Kansas State Board of Pharmacy "fictitious, false, misleading, or fraudulent material" in its Application for Renewal of its Kansas Non-Resident Pharmacy License. The Board granted applicant's request for pharmacy license and ruled as follows: **1) Applicant shall be licensed as a pharmacy; and 2) Applicant is hereby placed on probation for five years.**

17.23. May 3, 2017 Board Hearing

Homeland Pharmacy #886, #1-5886 – Case No. 1462: Admitted guilt on six counts including failing to keep and preserve in a suitable book, file, or record for a period of not less than five years every prescription compounded or dispensed at the pharmacy; failing to maintain and have readily retrievable for five years an original prescription; failing to hold the health and safety of its patrons as its first consideration; and violating patron confidentiality. **$5,000 fine.**

Calendar Notes

The Board will meet on **Wednesday, August 30, 2017,** and **Wednesday, October 4, 2017.** The Board will be closed **Monday, September 4** for Labor Day. Future Board dates will be available at *www.pharmacy.ok.gov* and will be noted in the October *Newsletter*.

Change of Address or Employment?

Please be diligent in keeping your information up to date and if possible, remind your coworkers and employees. 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.

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