



Oklahoma State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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



Season's Greetings

The members and staff of the Oklahoma State Board of Pharmacy would like to join in wishing everyone happiness and all the best for the coming year.

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50-Year Pharmacists Honored

The Oklahoma State Board of Pharmacy hosted a reception on October 8, 2015, in honor of the recipients of the 2015 Fifty Year Gold Certificate Award. Thirty-six Oklahoma pharmacists achieved 50 years of service to the profession of pharmacy and received the award in appreciation of their service and achievement.



Pictured left to right: Fifty-Year Recipients James Stanley, Marion Bloss, Roger Bayless, Harold Hutton, and Clarence Baker, and Board Member Mark St Cyr

From the Inspector's Desk

♦ **16.01. Phantom or Absentee PICs:** Several Oklahoma-licensed pharmacists have been approached by out-of-state pharmacies asking them to be employed as their pharmacist-in-charge (PIC) without requiring them to actually work at the pharmacy. PIC duties include accepting full responsibility of all aspects of the pharmacy's operation, including, but not limited to:

- ♦ Supervision of all employees as they relate to the practice of pharmacy, and
- ♦ Maintaining a proper record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs.

Oklahoma rules require that a pharmacy manager shall work sufficient hours in a pharmacy to exercise control and meet the responsibilities of the pharmacy manager. It would not be possible for a PIC to fulfill his or her responsibilities without being physically present in the pharmacy. The pharmacist would also have to be licensed in the resident state of the pharmacy.

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Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!



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.

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

6) Compounded Pain Creams: High Profit Margin and Danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been

FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

7) Clear Care: Still Causing Severe Eye Injuries Five Years Later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each



vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm.

US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at www.fda.gov/Safety/Recalls/ucm464071.htm.

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at www.fda.gov/Safety/Recalls/ucm464072.htm.

FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm.

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public

when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanyl. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at www.fda.gov/Drugs/DrugSafety/ucm458952.htm.

MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at www.fda.gov/Safety/Recalls/ucm461939.htm.

◆ **16.02. Electronic Prescriptions for Controlled Substances:**

Pharmacies with certified software may receive electronic prescriptions (including Schedule II-V) from prescribers with certified software. Electronic signatures for controlled dangerous substances (CDS) are only valid for prescriptions that have been transmitted electronically on approved software. Electronic prescriptions should be continued to be stored electronically and do not need to be printed by the pharmacy. If a controlled electronic prescription is unable to be filled at a pharmacy, that pharmacy may not transfer it to another pharmacy. The pharmacy must contact the prescriber and the prescriber must transmit it to the filling pharmacy.

Faxed prescriptions are not electronic prescriptions by Drug Enforcement Administration (DEA) definition and must be manually signed by the prescriber prior to being faxed. Prescriptions may not be emailed as this is not a secure method of transmittal and is not compliant with the Health Insurance Portability and Accountability Act of 1996.

◆ **16.03. Pharmacies Registering as Authorized Collectors:**

To encourage citizens to properly dispose of unused medications and prevent and reduce prescription drug abuse, DEA has passed legislation that allows some DEA registrants, such as retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, and reverse distributors, to modify their registration with DEA to become authorized collectors. Authorized collectors may maintain collection receptacles and administer mail-back programs.

The Oklahoma Bureau of Narcotics (OBN) has also changed its statutes to allow registrants to collect CDS and non-CDS in accordance with DEA regulations. Visit www.dea diversion.usdoj.gov/drug_disposal/index.html for more information. Keep in mind that the OBN also has prescription disposal boxes for the proper disposal of medications by citizens in many locations throughout the state, and those may be located by accessing <https://portal.obn.ok.gov/takeback/default.aspx>. All registrants, including pharmacies and prescribers, must utilize reverse distributors or their wholesalers for proper disposal of any CDS for proper accountability.

◆ **16.04. Drug Diversion Detection and Prevention Plan**

Guide: Compliance officers continue to check for drug diversion detection and prevention plans during routine inspections. If you do not have one or if you need to update your plan, a guide is available to assist you and can be found on the Board's website at https://www.ok.gov/OSBP/Forms_for_Download/Pharmacies/index.html.

Disciplinary Actions

For more information, you may view hearing minutes at <https://www.ok.gov/OSBP/Minutes/index.html>.

16.05. October 21, 2015 Board Hearing

Linda France, DPh #12079 – Case No. 1294: Agreed to guilt on 564 counts including allowing a non-pharmacist to perform duties reserved to a pharmacist; allowing persons to perform clerical tasks who are not regularly paid employees of the pharmacy; failing to have a proper record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs; violating patient confidentiality; failing to properly label and store hazardous drugs separately from other drugs; failing to mix, prepare, and otherwise manipulate, count, crush, compound powders, or pour liquid hazardous drugs inside a ventilated cabinet; failing to prepare and review all compounding records to ensure that no errors have occurred in the

compounding process; failing to prepare compounded preparations that contain not less than 90% and not more than 110% of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume, and not less than 90% and not more than 110% of the theoretically calculated weight or volume per unit of the preparation. **Fourteen-day suspension from October 26, 2015, to November 9, 2015. Probation from November 10, 2015, until November 1, 2017. Shall not work as a PIC. 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 2016 and 2017. All 15 hours of required CE that respondent must have to renew her license shall be live during the years 2016, 2017, 2018, 2019, and 2020. Respondent shall successfully complete a Board-approved seminar on compounding.**

Arcadia Pharmacy Solutions LLC, #2-7217 – Case No. 1296:

Agreed to guilt on 786 counts including allowing a non-pharmacist to perform duties reserved to a pharmacist; allowing persons to perform clerical tasks who are not regularly paid employees of the pharmacy; failing to have a proper record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs; violating patient confidentiality; failing to properly label and store hazardous drugs separately from other drugs; failing to mix, prepare, and otherwise manipulate, count, crush, compound powders, or pour liquid hazardous drugs inside a ventilated cabinet designed to prevent hazardous drugs from being released into the work environment; failing to use a high-efficiency particulate air filter for the exhaust; failing to prepare and review all compounding records to ensure that no errors have occurred in the compounding process; failing to prepare compounded preparations that contain not less than 90% and not more than 110% of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume, and not less than 90% and not more than 110% of the theoretically calculated weight or volume per unit of the preparation; failing to verify all critical processes to ensure that procedures will consistently result in the expected qualities in the finished preparation; misfilling a prescription or drug order that departs from the standards of care ordinarily exercised by a registrant; entering into an arrangement whereby prescription orders are received or prescriptions delivered at a place other than the pharmacy in which they are compounded and dispensed; filling or refilling a prescription for a dangerous drug without authorization; failing to ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner acting in the usual course of the practitioner's professional practice; filling prescriptions issued by individual practitioners for the purpose of obtaining CDS to stock or resupply their office or medical bags in order to generally dispense to patients; dispensing a prescription drug when registrant knew or should have known that the prescription was issued without a valid pre-existing patient-practitioner relationship; and submitting fraudulent billing or reports to a third-party payer of prescription drugs. **\$15,000 fine. License revoked.**

Alexy Blackmon, Technician #10419 – Case No. 1345: Found guilty on three counts including possession of a CDS without a valid prescription and committing theft while working as a registrant. **Revoked.**

Teresa Badillo, Technician #3945 – Case No. 1354: Found guilty on three counts including possession of a CDS without

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a valid prescription and committing theft while working as a registrant. **Revoked.**

Shauna Stacey, Technician #17398 – Case No. 1355: Found guilty on three counts including committing theft while working as a registrant. **Revoked.**

Christina Essary, Technician #14454 – Case No. 1356: Found guilty on four counts including failing to establish and maintain effective controls against the diversion of prescription drugs and filing a report or record that the registrant knows to be false. **Revoked.**

David Redden, DPh #14630 – Case No. 1357: Agreed to guilt on 21 counts including misfilling a prescription or drug order. **Shall attend a one-day (eight-hour) law seminar in addition to the required 15 hours of CE during the calendar year of 2016. All 15 hours of required CE that respondent must have to renew his license shall be live during the years 2016 and 2017.**

Deanna Sparks, DPh #15046 – Case No. 1358: Agreed to guilt on five counts including forging or increasing the quantity of drug in any prescription or presenting a prescription bearing forged, fictitious, or altered information or possessing any drug secured by such forged, fictitious, or altered prescription, and theft while practicing pharmacy. **Five years' probation until October 21, 2020, and \$6,000 fine.**

Wheeler & Stuckey Rx Pharmacy No. 2, #1-959 – Case No. 1362: Agreed to guilt on five counts including failing to have available for inspection at the pharmacy location a policy and procedure manual dealing with sterile therapeutic preparations and services; failing to have available for inspection at the pharmacy location a policy and procedure manual that has been reviewed and/or revised on an annual basis; failing to have a pharmacy manager who is knowledgeable in the specialized functions of compounding, preparing, and dispensing sterile therapeutic preparations; failing to have a documented, ongoing quality assurance program; and failing to install a pressure gauge or velocity meter to monitor the pressure differential or airflow between the cleanroom and the general environment outside the compounding area. **Five years' probation until October 21, 2020. \$10,000 fine. Pharmacy's sterile compounding permit is suspended until respondent is in compliance with all aspects of United States Pharmacopeia (USP) Chapter <797>.**

Dale Metzler, DPh #8635 – Case No. 1363: Agreed to guilt on 14 counts including failing to be familiar with all details of USP compounding standards; failing to have available, follow, and retain written policies and procedures for all steps in the compounding of preparations; failing to ensure that all compounders who compound pharmaceuticals meet all requirements for training, testing, and education; failing to have a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities; failing to ensure proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice; failing to make sure that total aseptic techniques, including gowning, mask, and hairnet, are used when preparing high-risk sterile products; failing to remove all outdated prescription drugs from the active inventory area upon expiration; making or filing a report or record that he knew or should have known to be false; falsely marking, altering, forging, or counterfeiting any instrument in writing, being or purporting to be any license or authority authorized by any statute; and failure to cooperate in Board investigations. **Five years' probation until October 21, 2020. \$28,000 fine.**

Shall attend a one-day (eight-hour) law seminar in addition to the required 15 hours of CE during the calendar years of 2015 and 2016. All 15 hours of required CE that respondent must have to renew his license shall be live during his five years of probation. Shall successfully complete a sterile compounding class of a minimum of 16 clock hours.

Bivens Drug, #70-5920 – Case No. 1364: Agreed to guilt on three counts including failing to be responsible for all aspects of the operation related to the practice of pharmacy and failing to remove all outdated prescription drugs from the active inventory area upon expiration. **\$3,000 fine.**

Jerry Lee Dennis, DPh #9252 – Case No. 1365: Agreed to guilt on two counts including failing to be responsible for all aspects of the operation related to the practice of pharmacy. **\$2,000 fine. Shall attend a one-day (eight-hour) Oklahoma Pharmacists Association law seminar in addition to the required 15 hours of CE during the calendar year 2016. All 23 hours of CE during 2016 shall be live.**

Calendar Notes

The Board will meet on **January 20** and **February 24, 2016**. The Board will be closed Friday, **January 1**, for New Year's Day; Monday, **January 18**, for Martin Luther King, Jr Day; and Monday, **February 15**, for Presidents' Day. Future Board dates will be available at www.pharmacy.ok.gov and will be noted in the April 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. Oklahoma Pharmacists Helping Pharmacists (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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John A. Foust, PharmD, DPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Deborah Zak - Communications Manager