



Oklahoma State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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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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From the Inspector's Desk

- ◆ **17.01. Electronic Prescriptions:** Schedule II-V prescriptions are allowed to be prescribed electronically. There is nothing that prevents an out-of-state **physician** from electronically prescribing controlled dangerous substance (CDS) prescriptions. However, pharmacists have a responsibility to confirm the legitimacy of the prescription. Additionally, all prescriptions received by a pharmacy should be stored in the manner in which they were received (ie, if you receive an electronic prescription, it should be stored electronically). If a hard copy prescription is received, a pharmacy may not scan the prescription and then shred the original. A facsimile (fax) is not considered an electronic prescription, and faxed prescriptions for CDS must be manually signed by the prescriber. Emailed prescriptions are not a valid form of electronic communication for any type of pharmacy, including those that service long-term care facilities, because they are not Health Insurance Portability and Accountability Act-compliant. Any pharmacies that engage in this practice should stop immediately.
- ◆ **17.02. Oklahoma Technician Exam:** The Oklahoma State Board of Pharmacy technician examination required for all pharmacy technicians licensed April 2012 or later is available on the Board website. The exam is attached to the new application for pharmacy technicians. This exam must be maintained and readily retrievable in the pharmacy for inspection. Please do not send the completed exam to the Board. Also, do not forget that technician training is required to be updated on an annual basis for all technicians. Documentation of annual training must also be maintained and be readily available in the pharmacy. If training is completed via computer, then print transcripts regularly and keep in the pharmacy to expedite inspections. It is time-consuming for pharmacists and compliance officers to obtain records off the computer, and many staff pharmacists do not know how to access those records. Records may not be maintained in another department, such as human resources.
- ◆ **17.03. Outdated Prescription Drugs:** Outdated drugs continue to be an issue in some pharmacies. All outdated drugs shall be removed from the active inventory upon expiration and cannot be used to fill or compound prescriptions. Outdated drugs must be removed from the pharmacy no later than six months past their expiration. This applies to "Rx

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FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at www.ecfr.gov.

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf. FDA provides more information online at www.fda.gov/Drugs/DrugSafety/ucm524320.htm.

Selected Medication Risks to Manage in 2017

 *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.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.¹ Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been

taken to increase staff awareness of the problem or improve the lighting.^{1,2} This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.^{1,2}

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.^{3,4} Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.⁴ Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.⁴ Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.⁴ Medication rooms should provide illumination at 100 fc.⁴ Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy³ and should be used on mobile medication carts (including those used with bar code medication verification systems)⁴ and near ADCs.

References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

News to a particular state or jurisdiction can only be ascertained such state or jurisdiction.

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at www.dea.gov/divisions/hq/2016/hq100416.shtml and in the final order available at <https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf>.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, “Pharmacists: On the Front Lines,” offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA’s news release indicates the changes are part of the agency’s Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm.

FDA’s Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information 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 drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/DDIWebinars.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will “alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse.” In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at www.fda.gov/Drugs/DrugSafety/ucm526206.htm.

Latest FDA Drug Info Rounds Training Videos Available

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, “Extortion Scam,” pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA’s 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.

only” drugs as well as any ingredient used to compound prescription drugs. The Board has had to take action on some pharmacies that do not comply with this rule.

- ◆ **17.04. Advanced Practice Registered Nurse Prescribing:** Advanced practice registered nurses (APRNs) (whether they are clinical nurse specialists, certified nurse midwives, or certified nurse practitioners) may apply for authority to prescribe from the Oklahoma Board of Nursing. They must prescribe within their specialty area of practice. If they are prescribing CDS, they must be registered with Drug Enforcement Administration (DEA) and the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBND).

APRNs have an exclusionary formulary or a list of medications they are not permitted to prescribe. A few of the medications included in that list are all Schedule IIs, clozapine, and ketamine. Only certified registered nurse anesthetists (CRNAs) may select, obtain, order, and administer Schedule IIs. CRNAs may not write outpatient prescriptions.

APRNs may prescribe no more than a 30-day supply of Schedule III-V medications, including refills. The Board of Nursing rules do not limit the days supply for non-controlled prescriptions. The Board of Nursing requires that the supervising physician be listed on all prescriptions issued by APRNs. APRNs may not dispense medications from their office, but they may distribute samples.

If an APRN is working in an emergency room, he or she must function within the scope of practice for the selected area of specialization. An APRN does not have the authority to order Schedule II prescription medications for his or her patients based upon a protocol. An APRN may utilize his or her registered nurse license and take a verbal order for a Schedule II from a physician in a hospital setting, which must be signed within the appropriate time frame by the physician.

- ◆ **17.05. Physician Assistant Prescribing:** Physician assistants (PAs) may prescribe up to a 30-day supply of Schedule III-V medications, but refills are not permitted. A PA may not write an outpatient prescription for a Schedule II. He or she must prescribe within the limitations of a formulary that is set forth by the Oklahoma Medical Board. If he or she is prescribing CDS, he or she must be registered with DEA and the OBND.

Non-controlled drugs prescribed for a new diagnosis are limited to a 30-day supply with two refills. Non-controlled drugs prescribed for an established diagnosis are permitted up to a 90-day supply with three refills. A PA may not dispense but may distribute samples.

The Medical Board requires the supervising physician be listed on the prescription. If more than one physician is listed on the prescription, then the PA shall indicate which one is the supervising physician. A PA may not order any medications that his or her supervising physician is not permitted to prescribe.

In a hospital or clinical setting, a PA may write an order for a Schedule II for immediate or ongoing administration on site based on a written protocol determined by the supervising physician and approved by the medical staff. In the absence of a protocol, a PA may also take a verbal order for a Schedule II from a physician, which must be signed by the physician within the appropriate time frame.

Board rules do not allow pharmacies to fill any prescriptions for out-of-state mid-level practitioners, including APRNs, PAs, or optometrists. If an out-of-state mid-level practitioner is also licensed in Oklahoma and is supervised by an

Oklahoma-licensed physician, his or her prescription may be filled in Oklahoma.

- ◆ **17.06. Theft and Diversion:** Compliance officers highly recommend that pharmacies adopt a policy of only allowing clear drinking containers in the pharmacy. The Board has had several cases involving large Styrofoam cups, one of which recently resulted in the theft of over 14 pints of promethazine with codeine syrup. Termination for theft or any other violation of the Oklahoma Pharmacy Act **must** be reported to the Board. The Board will investigate and will not take action without adequate evidence.
- ◆ **17.07. Pharmacist Licensure Display:** Pharmacists are required to attach their current license renewal receipt to the lower left corner of their original (ie, “big”) certificate. Relief pharmacists may post a copy of their renewal receipt in the pharmacies where they work or carry their renewal receipt with them. Do not make a copy of your original certificate.

Disciplinary Actions

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

17.08. September 28, 2016 Board Hearing

Jones Drug Store, #1-1914 – Case No. 1422: Admitted to guilt on four counts including failing to ensure that only a pharmacist is responsible for the control and distribution of all drugs; failing to establish and maintain effective controls against prescription errors or misfills; failing to ensure that all tasks performed by pharmacy technicians are performed under the immediate and direct supervision of a pharmacist who is currently licensed by the Board; and permitting the practice of pharmacy by someone other than a licensed pharmacist or assistant pharmacist. **\$1,250 fine.**

Phillip Hal Abel, DPh #8223 – Case No. 1423: Admitted to guilt on four counts including failing to establish and maintain effective controls against prescription errors or misfills; failing to ensure that all tasks performed by pharmacy technicians are performed under the immediate and direct supervision of a pharmacist who is currently licensed by the Board; failing to have the pharmacist certify a completed prescription by reviewing the prescription for accuracy and completeness before the prescription is released; and permitting the practice of pharmacy by someone other than a licensed pharmacist or assistant pharmacist. **\$1,250 fine. Respondent shall attend a one-day (eight-hour) law seminar in addition to required 15 hours of continuing education (CE) during the calendar year of 2016.**

Spechal Pete, Technician #21586 – Case No. 1424: Found guilty on four counts including committing theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

Chantel Lavern Carroll, Technician #12339 – Case No. 1426: Admitted to guilt on four counts including committing theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

Derreck Edwards, Technician #20514 – Case No. 1427: Found guilty on four counts including committing theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

Impaired Pharmacist, DPh #14338 – Case No. 1433: Admitted to guilt on five counts including possession of a CDS without a valid prescription and theft while practicing pharmacy. **Suspended for 10 years until September 28,**

2026. Suspension is immediately stayed and placed on probation until September 28, 2026. Respondent must enter into and abide by a 10-year contract with Oklahoma Pharmacists Helping Pharmacists (OPHP). Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of live CE during the calendar years of 2017 and 2018 for a total of 23 hours of CE each year.

Curtis Townsend, DPh #9999 – Case No. 1435: Admitted to guilt on three counts including failing to establish and maintain effective controls against the diversion of prescription drugs. **\$2,500 fine. Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of live CE during the calendar years of 2017 and 2018 for a total of 23 hours of CE each year. Respondent shall attend diversion prevention classes of no less than three hours in duration during either 2017 or 2018. Respondent must complete 15 hours of live CE during the calendar year of 2017.**

17.09. November 2, 2016 Board Hearing

Michael Brent Moore, DPh #10778 – Case No. 1373: Failure to pay Board fine. \$88,858 balance of January 20, 2016 Board fine is due by April 29, 2017.

Verlinda Johnson, Technician #21186 – Case No. 1425: Found guilty on one count of committing theft while working as a registrant. **Revoked.**

Sarah Van Horn, Technician #19902 – Case No. 1428: Found guilty on four counts including committing theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

Impaired Pharmacist, DPh #14486 – Case No. 1429: Admitted to guilt on two counts including violating a voluntary or Board-ordered rehabilitation program for the impaired contract. **One-year suspension until November 2, 2017. Respondent shall extend her contract with OPHP until November 2, 2026. All 15 hours of required CE shall be live during the calendar years of 2016 through 2026.**

Prescriptions Compounding Pharmacy, #2-5915 – Case No. 1430: Admitted to guilt on 869 counts including shipping prescriptions out-of-state without being licensed in those states during 2013-2015. **\$10,000 fine.**

Alexis Nguyen, DPh #16318 – Case No. 1431: Neither admits nor denies guilt on nine counts including incorrectly filling or misfilling a prescription or drug order and failing to establish and maintain effective controls to prevent prescription errors. **\$2,000 fine. Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of live CE during the calendar years of 2017 and 2018 for a total of 23 hours of CE each year. Respondent shall attend error prevention classes of no less than three hours in duration during the calendar years 2017 and 2018.**

Walgreens #10836, #14-7114 – Case No. 1432: Neither admits nor denies guilt on nine counts including incorrectly filling or misfilling a prescription or drug order and failing to establish and maintain effective controls to prevent prescription errors. **One-year probation until November 2, 2017. \$6,000 fine. Respondent shall review 50 prescriptions per day for errors as part of its error prevention program while on probation. All pharmacists and technicians currently employed or employed by respondent between November 2, 2016, and November 2, 2017, shall successfully complete the Institute for Safe Medication Practices questionnaire for Improving Medication Safety in Community Pharmacy: Assessing Risk and Opportunities for Change.**

Select HME, #9-D-777 – Case No. 1434: Admitted to guilt on eight counts including failing to conform to the *Compressed Medical Gases Guideline* published by the United States Department of Health and Human Services and Food and Drug Administration; failing to employ personnel who have sufficient education, training, and/or experience to perform assigned functions; failing to establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, and distribution of drugs; and failing to maintain or provide a complete and accurate record. **\$2,000 fine. Respondent will no longer transfill medical grade gases as of November 2, 2016.**

Impaired Pharmacist, DPh #13663 – Case No. 1436: Admitted to guilt on two counts including violating a voluntary or Board-ordered rehabilitation program for the impaired contract. **Ten-year suspension stayed and placed on probation until November 2, 2026. Respondent must enter into and abide by a 10-year contract with OPHP. Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of live CE during the calendar years of 2017 and 2018 for a total of 23 hours of CE each year.**

Calendar Notes

The Board will meet on **Wednesday, January 25, 2017, and Wednesday, March 29, 2017.** The Board will be closed **Monday, January 2** for New Year's Day; **Monday, January 16** for Martin Luther King, Jr Day; and **Monday, February 20** 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. 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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