OKLAHOMA STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

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National Pharmacy Compliance News A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

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24.124 Retirement of Mary Ann Terral and Gary LaRue

The Oklahoma State Board of Pharmacy would like to extend its warmest wishes to Mary Ann Terral and Gary LaRue on their recent retirement from the Board. Mary Ann began her journey with the Board as the business manager in January 1986 and retired as such on February 1, 2024. Gary began his journey as a compliance officer in June 2000, staying in that position until he was promoted to deputy director in 2020. He retired on January 1, 2024. The Board and staff would like to thank Mary Ann and Gary for their outstanding work and dedication to the Board. The Board wishes Mary Ann and her husband, Ken, and Gary and his wife, Lana, the very best.

24.125 Death Notices

To respect families who have lost loved ones, please notify the Board as soon as possible if you have an employee or know of a licensed registrant who has passed away. This will prevent the family from receiving information from the Board such as renewal notices and email blasts.

24.126 Compliance With Income Tax Laws

Effective November 1, 2023, the Oklahoma Tax Commission (OTC) will no longer notify the board of licensee compliance with Oklahoma income tax laws. The Board will not be required to place a tax hold on the license, causing a delay in renewing. Each licensure board will still be required to continue submitting a complete list of license holders for the OTC to ensure compliance with Oklahoma income tax laws. Any licensee not in compliance with Oklahoma income tax laws due to delinquent returns or outstanding balances may be subject to wage garnishment and/or an audit.

24.127 Online Renewal Payments

The Board has seen a spike in duplicate payments for pharmacy technician and pharmacist renewals. Renewals are to be completed online unless you have prior approval to send the Board a paper renewal. You will be prompted to make a payment after you have logged in to your account and completed the online renewal process. The payment process for online renewals is different than making a payment through the online store. Please contact the Board if you have any questions.

24.128 Requirements for Oklahoma Technicians

The Board has had some recent instances of sites that are not in compliance with the regulations pertaining to technician requirements, including incomplete training. Please be certain that all staff members at your location are aware of these requirements and are compliant with the rules. There are many sections in the law book that address such requirements, and all staff should be familiar with them. They include, but are not limited to, Oklahoma Administrative Code (OAC) 535:15-13-4, OAC 535:15-13-8, and OAC 535:15-13-13.

24.129 Registrant Responsibility to Ensure Compatibility of Dosage Forms

If any registrant is using a Customized Adherence Medication Package (CAMP), please be aware that the software (eg, Dispill) may not be checking for physical and chemical compatibility of the dosage forms. It is the registrant's responsibility to check for the following, per OAC 535:15-18-3 – Packaging requirements:

(3) When preparing a CAMP, the dispenser shall take into account any applicable USP Compendial requirements or guidelines, the physical and chemical compatibility of the dosage forms placed within each container, and any therapeutic incompatibilities that may affect the simultaneous administration of the medications. Medications shall not be dispensed in CAMP in any of the following situations:

(A) The USP monograph or official labeling of a medication requires dispensing in the original container.

(B) The drugs or dosage forms are incompatible with packaging components or each other.

(C) The drugs are therapeutically incompatible when administered simultaneously.

Verify all services provided with your CAMP software and be mindful that you are responsible for anything they are not providing.

24.130 Labeling Requirements for Veterinary Prescriptions

If your site is dispensing a prescription for an animal, the following addresses the labeling requirements for such dispensing. Please note that both the patient and the client's name shall be included on the prescription label, along with the client's address, if the drug is a controlled dangerous substance.

OAC 775:25-1-3. Dispensing and Labeling Requirements

(a) All controlled dangerous substances and veterinary prescription drugs lawfully possessed and to be dispensed for use by a companion animal shall be dispensed only on the order of a licensed veterinarian who has an existing veterinary-clientpatient relationship as defined by the Act and the rules of the Board. The veterinarian shall ensure that labels will be affixed to any unlabeled container containing any medication dispensed and to each factory labeled container that contains veterinary prescription drugs for companion animals. The label shall be affixed to the immediate container and shall include the following information:

(1) the name and address of the dispensing veterinarian, and the veterinarian's telephone number if the drug is a controlled dangerous substance;

(2) the date of delivery or dispensing;

(3) the name of the patient, the client's name, and the client's address if the drug is a controlled dangerous substance;

(4) the established name or active ingredient of the drug, strength, and quantity of the drug dispensed;

(5) directions for use specified by the practitioner including dosage, frequency, route of administration, and duration of therapy; and

(6) any cautionary statements required by law, including the words "For Veterinary Use Only", and/or any withdrawal periods associated with the drug. If the size of the immediate container is insufficient to be labeled, the small container shall be enclosed within another container large enough to be labeled.

24.131 Elevating Accuracy in Pharmacy Compounding: The Importance of Correct Weighing Techniques and Understanding Your Analytical Balance

By Heith A. Crosby, PharmD, PhD, BCSCP, RCP-SCF

In pharmacy, the accuracy of every weighed ingredient is fundamental to ensuring the safety and effectiveness of medications. OAC Section 535:15-10-8 highlights the critical need for accurate weighing, measuring, and subdividing of components, emphasizing the necessity for pharmacists to maintain the highest standards in their practice. This focus on accuracy draws attention to the crucial role of analytical balances and the significant risks posed by weighing substances at their readability limits.

Risks of Weighing at Readability Limits

Weighing a substance at a balance's readability limit (d), such as 1 mg on a balance with a 1 mg readability, significantly increases the risk of error. For example, if an item that actually weighs 1.9 mg is measured on balance with a 1 mg readability, the potential for a 47.37% error exists and starkly illustrates the necessity for accurate measurement practices. Such errors highlight the balance's technical limitations at the edge of its readability and raise concerns over the potential impact on the quality and integrity of compounded medications.

Best Practices for Enhanced Accuracy

Pharmacists must implement best practices in their weighing operations. Depending on the specific use, one can refer to United States Pharmacopeia Chapters <41>, <795>, <1163>, <1176>, <1251>, and the Board of Pharmacy Rules for guidance. Selecting balances with the appropriate readability for the substances being weighed, ensuring the regular calibration and maintenance of these instruments, determining the balance's minimum weighable quantity, and following rigorous documentation and verification processes are essential. These measures support achieving accurate and reproducible results and safeguard the integrity of compounded pharmaceutical preparations and patient safety.

Conclusion

A commitment to accurate measurement practices underpins the path to excellence in pharmacy. By recognizing the challenges associated with the readability of analytical balances and adhering to best practices and guidelines, pharmacists can avoid significant measurement and compounding errors. This commitment to accuracy in all measurements reflects the pharmacy profession's core values and ensures high-quality patient care. As pharmacists strive for continuous improvement in the practice, remember the critical importance of accuracy in maintaining the health and well-being of the communities served.

24.132 Disciplinary Actions

Texas Star Pharmacy, #99-8411 – Case No. 1675: Fined \$3,000 per count, for a total fine of \$9,000. Respondent will pay for investigative costs agreed upon by the parties. Respondent shall continue to test initial potency, endotoxin, and sterility of all batches that include 25 or more vials of compounded semaglutide. Respondent shall have an inspection by third party on an annual basis for the next three years. The first report is due on November 30, 2024, and will continue annually until November 30, 2026. Inspection reports will be sent to the Board.

Daniel J. Keller, DPh #19432 – Case No. 1676: Fined \$2,000 per count, for a total fine of \$6,000. All continuing education (CE) for the years 2024 and 2025 shall be live. Respondent will attend the annual law seminar for the years 2024 and 2025.

(Impaired DPh) #11936 – Case No. 1682: Respondent's license is indefinitely suspended. Respondent will enter into and remain compliant with a lifetime contract with Oklahoma Pharmacists Helping Pharmacists (OPHP). Once respondent has been determined "fit for duty" and the Board has received a recommendation from OPHP supporting an active license, respondent may petition the Board to request their pharmacist license be reinstated. Respondent shall complete 15 hours of CE for two consecutive calendar years. Respondent is required to complete a substance use disorder conference or seminar that is OPHP approved. Respondent is found guilty on two counts, including the requirement that a registrant conduct themselves at all times in a manner that entitles them to the respect and confidence of the community in which they practice.

Calendar Notes

Upcoming Holidays: The Board office will be closed on May 27, 2024, for Memorial Day, and July 4, 2024, for Independence Day.

Upcoming Board Meeting: The Board is scheduled to meet on April 17, 2024. All meetings begin at 8:30 AM.

New Fax Number

The Board has received a new fax number. When sending faxes to the Board office, please use 405/900-8365. Please discontinue using 405/521-3758 to send faxes.

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. Address and employment changes can no longer be made on the online renewal system. Emailed notifications can be sent to pharmacy@pharmacy.ok.gov or faxed to 405/900-8365. License/ permit numbers must be included to be accepted.

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.

OPHP Helps Pharmacists in Need

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 helpline 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. [74 O.S. §3105 and 65 O.S. §3-114]

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