Kansas Board of Pharmacy

NEWSLETTER

Compliance | Licensing & Registration | K-TRACS

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What's Inside:

2024 Pharmacist Renewal

Pharmacist license renewal will be open in mid-May through June 30, 2024. Pharmacists are required to have completed 30 hours of ACPE/Board approved CE between **July 1, 2022, and the date of their renewal (no later than June 30, 2024)**. There is no grace period for completion of CE. For ways to reduce your CE audit risk, see the Board's June 2018 Newsletter.

If you renew online and answer "No" to all disciplinary questions, you can immediately print your 2024 pharmacist license renewal license (NEW FORMAT). **The Board will not print/mail these items.** If you answer "Yes" to a disciplinary question, you can verify your renewal has been received by visiting the License Verification page and checking for the updated expiration date, please allow 10-15 business days for review.

New Pharmacist CE Requirement

K.A.R. 68-1-1b(b)(2) requires pharmacists to complete a 1-hour CE provided by the Board. This 1-hour CE counts as 1 of the 30 total CE hours required for pharmacist licensure renewal and its completion is **required beginning with the June 2024 license renewal period**. The required course for 2024 and 2025 renewals is an ACPE-approved online course titled "K-TRACS for Pharmacies: Good Data In, Good Data Out." When completing the course, please include the **correct Kansas license number, NABP ID and date of birth** so your course attendance can be accurately reported to CPE Monitor within 30 days of completion. No certificates are issued.

If you are a pharmacist whose license renews this year, you must have completed this CE prior to renewing your license. Failure to complete this CE before renewing may result in disciplinary action. Please note: This CE is not required for pharmacy technicians, but they may choose to complete it to apply toward their renewal CE requirements.

2024 Pharmacy and Facility Renewals

Pharmacy and other facility permits are eligible for renewal from mid-May through June 30, 2024. Facilities renewing in May or June must meet all renewal requirements prior to the expiration date (June 30). Review the Board's guidance document for acceptable inspection types for non-resident facilities.

Manufacturers (4-) and Outsourcing Facilities (20-) should allow 15 business days for Board review and approval. Once approved, the facility can log back in and print/download a copy of the renewed permit. All other facilities may **immediately** print the 2024-2025 renewal permit. The Board office will not mail out renewal certificates.

Statement on Compounding and Dispensing of Compounded Semaglutide and Other GLP-1 Receptor Agonists

The compounding of semaglutide and other glucagon-like peptide-1 (GLP-1) receptor agonists by pharmacies and outsourcers has risen due to the FDA shortage status of Wegovy® and Ozempic®. Under the federal Food Drug & Cosmetic Act (FD&C Act) and Board regulations, compounding "drug products that are essentially copies of a commercially available drug product" is prohibited unless either of the following exceptions occurs:

1. The drug is not readily available and is listed on the FDA drug shortage list, or
2. There is a specific change for an identified patient whose medical needs cannot be met by the commercially available product.

While correctly applying either of the above exceptions prevents FDA action on compounding drugs that are essentially copies of a commercially available drug product, compounders must ensure that compounded bulk drug substance complies with FDA Bulk Drug Substance Requirements. When a drug is in shortage, compounders may be able to prepare a compounded version of that drug if they meet certain requirements in the FD&C Act.

When compounding of a semaglutide drug product is allowed under the FD&C Act, substances used to compound must:

1. comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding;
2. if such a monograph does not exist, be components of drugs approved by the Secretary of HHS; or
3. if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary of HHS, appear on a list developed by the Secretary through regulation.

With respect to semaglutide:

1. There is no USP or NF monograph for semaglutide.
2. Ozempic™ and Wegovy™ contain semaglutide base – not a salt form. Therefore, only the base is a component of an FDA-approved human drug product. The salt forms are different active ingredients than used in FDA-approved drugs, and do not meet FD&C Act requirements for compounding.
3. Semaglutide does not – in any form – appear on the FDA's "bulks list" for compounding. So, for this separate and independent reason, no salt form of semaglutide may be used in a compounded drug product.

Even if a pharmacy or outsourcing facility obtained semaglutide base for potential compounding use, the pharmacy or outsourcing facility must ensure that the API received is a pharmaceutical-grade product (not "research use only"), accompanied by a valid certificate of analysis, and is sourced from an establishment registered with the FDA.

The Board has determined that even when compounding of a semaglutide drug product is allowable under the FD&C Act, the use of semaglutide salts, the use of any non-pharmaceutical grade API, or one not produced by an FDA-registered establishment, is prohibited. Likewise, pharmacist dispensing of semaglutide that has been

compounded in a non-compliant manner (even if lawfully purchased) is prohibited because the compound does not qualify as a "drug" as defined by Kansas law. Any violation of the FD&C Act, the Kansas Pharmacy Act, or any rule or regulation thereunder may result in disciplinary or enforcement action by the Board and/or the FDA.

Adding additional substances to a compounded product that is otherwise an essential copy of a commercially available drug product is not included in FDA's list of circumstances meeting Section 503A(b)(2)'s requirements. If a change is made to the commercially available product for an identified individual patient and the prescribing practitioner has determined that the change will produce a significant difference for that patient, there is still a minimum threshold. The FDA has stated that "if a prescription identifies only a patient name and drug product formulation, this would not be sufficient to establish that the prescriber made the determination described by section 503A(b)(2). Note also that the significant benefit that the prescriber identifies must be produced by the change the compounder will make to a commercially available drug product (i.e., a change in drug product formulation). Other factors, such as a lower price, are not sufficient to establish that the compounded drug product is not essentially a copy of the commercially available drug product."

Drug manufacturers have become aware of the practice of using semaglutide salts for compounding and may choose to initiate legal proceedings to combat illegal compounding.

Notice to Consumers/Patients

Consumers should be reminded that these medications are legitimately available by prescription only, and should only be prescribed in direct consultation with, and under the supervision of, a licensed healthcare professional.

"FDA has received adverse event reports after patients used compounded semaglutide. Patients should not use a compounded drug if an approved drug is available to treat a patient. Patients and health care professionals should understand that the [FDA] does not review compounded versions of these drugs for safety, effectiveness, or quality."

"Patients should be aware that some products sold as 'semaglutide' may not contain the same active ingredient as FDA-approved semaglutide products and may be the salt formulations. Products containing these salts, such as semaglutide sodium and semaglutide acetate, have not been shown to be safe and effective.

Patients should only obtain drugs containing semaglutide with a prescription from a licensed health care provider, and only obtain medicines from state-licensed pharmacies or outsourcing facilities registered with FDA."

Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss | FDA

Complaints and Referrals

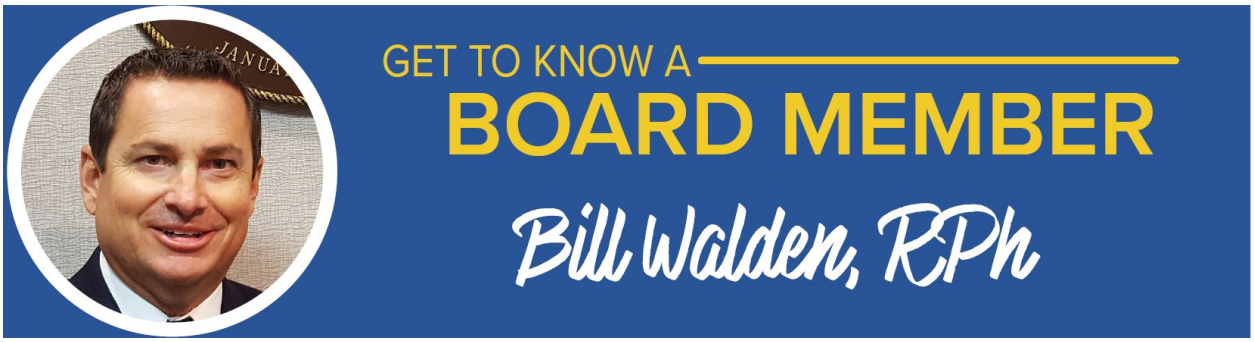
Complaints regarding distributors, pharmacies, or pharmacy personnel should be sent to the Board using the C-100 Complaint Form.

If you become aware of a non-pharmacy healthcare practitioner (i.e., physician, nurse, or APRN) engaged in compounding of semaglutide or other GLP-1 receptor agonists that you suspect does not conform to the FDA

requirements, the Board recommends filing a complaint with the respective regulatory authority, such as the Board of Healing Arts, Board of Nursing, or the FDA.

References:

- K.S.A. 65-1626(r) and (w), 65-1627(a) and (e), 65-1626a, 65-1657(f)
- K.A.R. 68-13-2, 68-13-3,
- FD&C Act § 503A(b)(1)(A)(i)-(iii), (b)(1)(D), (b)(2),
- Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov)
- Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov)
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov)
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov)



Bill Walden, RPh, joined the Board in 2017 and was re-appointed in 2021. During his 7-year tenure, he has developed relationships with Board members, stakeholders and Board staff that has made the experience one of the most rewarding of his professional career.

"I truly believe that the Board makes decisions that best protect our patients and serves our pharmacists and pharmacies throughout Kansas," Walden said. Walden says accomplishments during his tenure include the Board's reduction from 7 days to 3 days of the prospective review of hospital patients and continued work to adopt new USP guidelines. He served as the Board's investigative member for 2 years, reviewing results of investigations and approving disciplinary recommendations for individuals and facilities.

"I honestly did not realize the amount of disciplinary hearings that the Board deals with on an annual basis. Listening to each one and making decisions on these hearings has definitely made me a better pharmacist," Walden said.

With pharmacy school graduations planned this month, Walden encourages new pharmacists to be flexible and willing to grow professionally. "Pharmacy is a very difficult field currently, and adding services that we can provide helps patients receive healthcare services more readily and affordably."

A native of Iola, Walden is a graduate of the University of Kansas School of Pharmacy and is a partner in Iola Pharmacy Inc., with divisions serving retail, hospital and long term care pharmacy.

Board Members Re-Appointed

Board members Erick Axcell, PharmD, Lawrence, and Andy Truong, PharmD, Wichita, have been re-appointed to the Board of Pharmacy for additional 4-year terms. They were first appointed in 2020. Axcell currently serves as the Board's Vice President and Chair of the Collaborative Practice Committee, while Truong is the Board's alternate investigative member.

Notice **Effective July 1, 2024, the fee for fingerprint-based background checks will increase to $57. The Board will have updated applications available on the website.**

Who Is Permitted To Be In A Pharmacy?

The Board adopted K.A.R. 68-2-24 concerning pharmacy owner responsibilities, which became effective on October 27, 2023. The new regulation indicates a person that has had any license or registration denied, revoked, or suspended by the Board is not permitted in a pharmacy. This includes working as a clerk. (Note: A person may be permitted if the licensee or registrant has subsequently been issued an active license or registration by the Board.)

Reminder: e-Prescriber Waivers

If the pharmacist receives a non-electronic prescription for a controlled substance in schedule II-V that contains an opiate, the pharmacist should be aware that the prescription **may** include the additional words “waiver” or “exempt.” Regardless, the pharmacist **shall not** be required to verify the validity of the waiver or exemption, either with the prescriber or the Board, regardless of whether the prescription includes or does not include any additional words. An explanation of the distinction between “exempt” and “waiver” can be found in the Guidance Document on ePrescribing.

While neither the letter of the law nor the Board’s interpretation requires a pharmacist to verify, the Board has reinforced their previous guidance on dispensing: each pharmacist must use their professional judgment in dispensing valid prescriptions.

Announcements

- **BOARD OF PHARMACY JOB OPENING – SENIOR ADMINISTRATIVE ASSISTANT**
- A flyer designed for pharmacies to post and promote well-being and zero tolerance of aggressive consumer behavior by pharmacy personnel has been released by APhA. Get your copy on their website here.
- The KU School of Pharmacy has announced dates for their 2024 Summer Camp. Find more information about dates and registration at rockcha.lk/RxCamp.
- The National Association of Boards of Pharmacy (NABP) has released three new examination videos on the NABP YouTube channel. The newly released videos include:
  - NABP's 5 Essential Tips for Test Day
  - Avoid Misconduct for NABP Exams
  - Performance Report Overview

  Watch the videos to learn more and visit the NABP website for information about the exams.

Compliance Corner

☐ Are You a Collector With the DEA?

Has your facility's DEA registration been modified to allow for installation of a collection box for controlled substances or participation in a mail-back program? Are you aware of the additional biennial inventory requirements for a collector? 21 CFR 1304.11(e)(7) lists additional biennial inventory requirements for mail-back packages and container liners. Check it out!

☐ Tech Ratio and Name Tags

K.A.R. 68-2-15 says each pharmacy technician shall wear a name tag with their name and pharmacy technician designation while performing pharmacy technician functions in a pharmacy. Therefore, any person wearing a pharmacy technician name tag is presumed to be on duty in this capacity and will be counted in the technician ratio regardless of whether they are performing technician duties at the time.

☐ Our Furry Friends

Those of us who are pet people know there is nothing better than returning home after a long day to a wagging tail or soft purr from one of our furry friends. However, during recent pharmacy visits, we have seen an increase in the number of pets that are joining their owners in the pharmacy, especially dogs. Unfortunately, this can create several issues. In addition to the dander and allergens that can permeate the pharmacy and cause problems for people who are allergic, pets in the pharmacy create insanitary conditions. The following statutes address adulteration, contamination and insanitary conditions:

- K.S.A. 65-656(m) "Contaminated with filth" applies to any food, drug, device or cosmetic not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.
- K.S.A. 65-657 The following acts and the causing thereof within the state of Kansas are hereby prohibited: … (b) The adulteration or misbranding of any food, drug, device or cosmetic.
- K.S.A. 65-668 A drug or device shall be deemed to be adulterated:

  (a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or

  (2)(A) if it has been produced, prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or

  (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or

  (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; …

Pets can be great friends. Due to the nature of our business, however, these friends need to stay out of areas that impact drugs and devices. We have a duty to our patients to minimize any conditions that would be considered insanitary or potentially lead to adulteration.

K-TRACS Update

☐ Dispenser Guide Update: Partial Fills, DEA Suffix & Phone Numbers

Effective August 1, 2024, the Board will begin enforcement of the following changes to the K-TRACS Dispenser Guide requirements. Please share this information with your pharmacy system vendor and/or IT staff to ensure changes are made by the deadline.

Partial fills must be reported correctly

If a pharmacy chooses to partially fill prescriptions in accordance with K.A.R. 68-20-19 and 68-20-20, then records submitted to K-TRACS must be reported accordingly. Accuracy of this information will help avoid scrutiny of multiple fills of a prescription for the same patient. The following applies to partial fill submissions to K-TRACS:

- **Partial Fill Indicator (DSP13):** Use code 00 to indicate the prescription is NOT a partial fill. Use code 01 to indicate the first partial fill, 02 the second, etc.
- **Quantity Prescribed (DSP22):** This data element is situational and should be reported on any prescription reported with anything other than code 00 in DSP13. The quantity prescribed should reflect the original quantity written on the prescription.

- **Quantity Dispensed (DSP09):** This data element is required for all prescriptions and should reflect the actual amount of medication dispensed to the patient. In the event of a partial fill, quantity dispensed will be less than quantity prescribed (DSP22).

DEA suffix situationally required

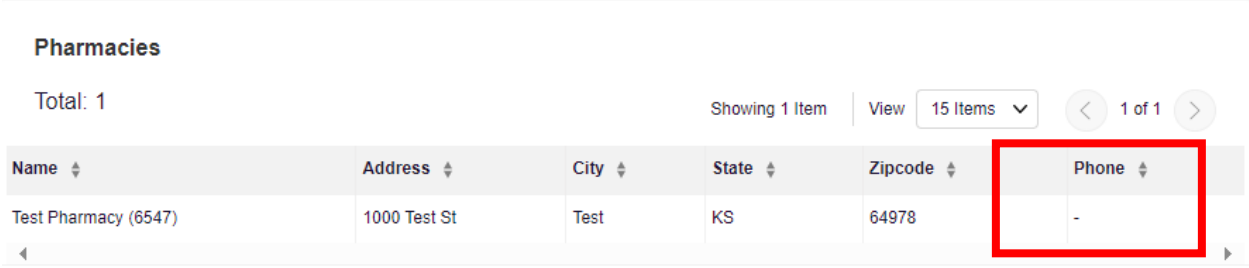
If a prescriber is prescribing under an institutional DEA number, a DEA suffix must be reported to K-TRACS to distinguish the prescriber.

- **DEA Suffix (PRE03)** is situational and should be included when known about a prescriber using an institutional DEA number.

Prescriber & dispenser phone numbers preferred

Pharmacies are encouraged to collect and report accurate prescriber phone numbers to facilitate care coordination using the K-TRACS report. Phone numbers reported for pharmacies and prescribers will display on the patient report along with the prescriber and pharmacy name and address. This contact information can be useful for healthcare providers to coordinate care for patients receiving multiple controlled substance prescriptions from multiple providers and/or pharmacies. Phone numbers should be updated when the pharmacy is notified of a change. The following fields are preferred, and pharmacies are encouraged to collect this information:

- Prescriber phone number (PRE08)
- Pharmacy phone number (PHA10)



Including a phone number for prescribers and pharmacies can help K-TRACS end users with care coordination.

☐ K-TRACS updates how-to guides

K-TRACS has updated a series of how-to documents as part of its user guide. The documents are available on the K-TRACS website to assist users with registering for accounts, conducting patient searches, updating account settings and more. Find helpful hints for using K-TRACS at Use K-TRACS (ks.gov).

☐ K-TRACS plans visits to Kansas pharmacies

In an effort to educate pharmacists and ensure accurate and timely reporting to K-TRACS, the K-TRACS pharmacist may visit Kansas pharmacies that dispense controlled substances. This is in conjunction with in-person visits by your pharmacy inspector. The K-TRACS pharmacist carries Board identification, similar to inspectors. K-TRACS may request to view copies of prescriptions, dispensing records, or other items pertinent to K-TRACS reporting requirements.

National News

Read the latest news from the National Association of Boards of Pharmacy
>> Read National News

Revoked Licenses & Registrations

In an effort to provide greater transparency to pharmacists, the Board will publish a list of revocations and suspensions against Kansas pharmacists, interns, and technicians in its quarterly Newsletter. The Board encourages the pharmacist-in-charge to verify the registration status of all employed technicians at least twice a year (June and November are recommended). The Board's license verification website is a secure and primary source of credential verification information, as authentic as a direct inquiry to the Board.

Please take notice of the Board's revocation action taken on these licenses, permits, and registrations:

- Bassett, Deedra, 14-08799, Case 24-141
- Carvallo-Herrera, Saul, 24-116562, Case 24-164
- Cobos, Brooke, 24-115451, Case 24-142
- Cruz, Anthony, 14-109689, Case 24-144
- Dandurand, Benjamin, 1-15646, Case 21-051
- Fadul, Babikir, 14-18679, Case 24-145
- Foreman, Allen, 14-15647, Case 24-146
- Galliher, Kenzie, 14-113199, Case 24-147
- Galloway, Angela, 14-03739, Case 24-148
- Gonzalez, Isabella, 24-118205, Case 24-028
- Greenway, Ajani, 14-116339, Case 24-149
- Grimsley, Tanika, 24-113939, Case 24-150
- Hink, Bobbie, 24-121610, Case 24-163
- Holland, Barbara, 14-03329, Case 24-151
- Jimenez, Cynthia, 14-114606, Case 24-152
- Kajula, Ariana, 14-114023, Case 24-153
- Kellogg, Charlene, 24-114422, Case 24-154
- Lewis, Susan, 14-100447, Case 24-155
- Luangouthavong, Samuel, 14-17133, Case 24-156
- Moore, Jimicca, 14-16757, Case 24-157
- Orantes, Jose, 14-109887, Case 24-158
- Ricketts, Kendrick, 14-115370, Case 24-160
- Velasquez, Jordan, 14-116455, Case 24-162

Please take notice of the Board's suspension action taken on these licenses, permits, and registrations:

- Oland, Joseph, 14-111498, Case 24-183
- Ruse, Kevin, 1-100579, Case 24-027
- Smith, Janelle, 1-13421, Case 24-022