JUNE 2025

KENTUCKY BOARD OF PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

Pharmacy Permit, 3PL, and Outsourcer Facility Renewals

Pharmacy permits, third-party logistics provider (3PL) licenses, and outsourcer facility licenses expire on June 30, 2025. You must renew your permit/license online via the Licensure Gateway Portal. To begin the renewal process, you must be registered and designated as the facility administrator.

Pharmacies must verify or provide a complete listing of all licensed or registered employees. Paper renewal applications will no longer be accepted. All online renewals must be completed by 11:59 PM EDT on June 30. All renewals received after June 30 will be assessed a delinquent fee.

Licensure Gateway Portal Information

The Licensure Gateway Portal is a single portal to manage licenses, permits, and registrations associated with the Kentucky Board of Pharmacy. It grants access to online applications and printable licenses/permits. Any facility modifications, such as name, location, ownership, hours, or employees should be completed via Licensure Gateway.

Any facility modifications, such as name, location, ownership, pharmacist-in-charge (PIC)/facility contact person, officers/members, hours, or employees should also be completed through the portal.

Who has access to manage a pharmacy or other facility licensed or permitted by the Board?

The PIC (if applicable) will be the facility administrator. Additional facility administrators may be assigned once the administrator is registered in the Licensure Gateway.

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Licensure Gateway Portal Information *(cont)*

How do I register in the Licensure Gateway?

Proceed to the Licensure Gateway and select "Register" for a one-time registration.
If you are an administrator of an existing licensed or permitted facility, register a new profile and type in the license or permit number of the facility.

How do I request access to be the administrator of a facility?

Once in the Licensure Gateway, simply add the pharmacy or other facility as a place of employment using its license or permit number. Select "Request to be Admin," and Board staff will review and approve it.

Can there be more than one administrator of a licensed or permitted facility?

Yes.

Regulation Update

The following new or amended regulations are now in effect.

201 Kentucky Administrative Regulations (KAR) 2:480: The purpose of this new regulation is to provide minimum requirements for pharmacies located in Kentucky engaged in remote prescription processing conducted via telework and to establish rules for electronic supervision, as well as codify the process referenced in Kentucky Revised Statutes (KRS) 315.020(5) regarding remote order entry and electronic supervision.

201 KAR 2:030: This amendment adds a definition for "good standing." Good standing means that a license is not suspended, revoked, surrendered, conditioned under terms of probation, or otherwise in a status that restricts the activity of the licensee in any manner.

201 KAR 2:050: This amendment clarifies that all fees are nonrefundable, and an application expires one year after the date it is received by the Board.

201 KAR 2:210: This amendment reorders the sections of the regulation and adds sections and rules around the use of automated filling systems and final product verification. Please review the specific changes here.

201 KAR 2:370: This amendment defines "tamper-resistant secure container" as an enclosed container used in a tamper-resistant automated dispensing system (ADS), designed to prevent the opening of the container and the manipulation of medications prior to loading the ADS and after the contents of the container have been enclosed and verified by a pharmacist. This amendment also updates the definition for "long-term care facility" to exclude assisted living communities as defined in KRS 194A.710(2)(a).

201 KAR 2:465: This new regulation details the application process for nonresident pharmacies and clarifies language in KRS 315.0351. An "isolated transaction" qualifying a nonresident pharmacy to apply for a waiver for a permit has been defined as a transaction in which dispensing is limited to an established patient of the dispensing pharmacy, no more than three times per calendar year. The regulation details the required policies and procedures that the nonresident pharmacy must develop and maintain.

It is important that you review these changes and maintain compliance with these provisions of law.

Expansion of Buprenorphine Treatment via Telemedicine Encounter

Drug Enforcement Administration's Expansion of Buprenorphine Treatment via Telemedicine Encounter was scheduled to be effective March 21, 2025, but has been delayed to December 31, 2025. Notably, this delayed final rule will require pharmacists filling buprenorphine telemedicine prescriptions to verify that the identity of the individual picking up the prescription matches the name of the patient or a member of the patient's household. Until December 31, 2025, prescribers and pharmacists will continue prescribing and dispensing buprenorphine under the Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications.

GLP-1 Compounding Update

Board staff has received inquiries concerning the compounding of glucagon-like peptide-1 (GLP-1) medications such as semaglutide and tirzepatide. Semaglutide is a commercially available drug product marketed as Ozempic® and Rybelsus® for treating diabetes and as Wegovy® for weight loss. Tirzepatide is a commercially available drug product marketed as Mounjaro® for treating diabetes and as Zepbound® for weight loss.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) 503A(b)(1)(D) prohibits pharmacies from compounding "drug products that are essentially copies of a commercially available drug product."[1] In general, compounding pharmacies may not compound semaglutide or tirzepatide, which are commercially available drug products.

Further, 201 KAR 2:076 also prohibits the compounding of essential copies of a commercially available drug product unless authorized by 21 United States Code 353(a). This is enforceable by the Kentucky Board of Pharmacy for individuals or entities licensed or permitted by the Commonwealth.

On March 10 and April 28, 2025, Food and Drug Administration (FDA) provided the following timeline updates for compounders:

Tirzepatide: On March 5, 2025, the district court denied the plaintiffs' preliminary injunction motion in *Outsourcing Facilities Association v. FDA, 4:24-cv-00953 (N.D. Tex.)*. Therefore, consistent with FDA's February 11, 2025 update:

- For a state-licensed pharmacy or physician compounding under [S]ection 503A of the FD&C Act, the period of enforcement discretion described below has ended.
- For outsourcing facilities under [S]ection 503B, FDA does not intend to take action against compounders for violations of the FD&C Act arising from conditions that depend on tirzepatide injection products' inclusion on FDA's drug shortage list until March 19, 2025.

Semaglutide: On April 24, 2025, the district court denied the plaintiffs' preliminary injunction motion in *Outsourcing Facilities Association v. FDA, 4:25-cv-00174 (N.D. Tex.)* regarding compounded semaglutide. Therefore, consistent with FDA's March 10, 2025, update:

- For a state-licensed pharmacy or physician compounding, dispensing, or distributing semaglutide injection products under [S]ection 503A of the FD&C Act, the period of enforcement discretion (described below) has ended.

1 U.S. Food and Drug Administration. Section 503A of the Federal Food, Drug, and Cosmetic Act. FDA. https://www.fda.gov/drugs/human-drug-compounding/section-503a-federal-food-drug-and-cosmetic-act.

GLP-1 Compounding Update

(cont)

- For outsourcing facilities compounding, distributing, or dispensing semaglutide injection products under [S]ection 503B, FDA does not intend to take action for violations of the FD&C Act arising from conditions that depend on semaglutide injection products' inclusion on FDA's drug shortage list until May 22, 2025.[2]

When is the compounding of semaglutide or tirzepatide permissible?

FDA does not consider a drug to be "commercially available" if it appears on FDA's shortage list.[3] As is true of all drug products, pharmacists and pharmacies should regularly monitor FDA's shortage list at the link provided below.[3]

Also, the FD&C Act 503A(b)(2) states that a compounded drug product is not "essentially a copy" of a commercially available drug product if a change is made for an identified individual patient and the prescribing practitioner has determined that the change will produce a significant difference for that patient.[1] FDA has explained:

> However, 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 [S]ection 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 ([ie], a change indrug 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.[4]

Is adding another commercially available drug, such as B12, still considered compounding a commercially available drug product?

FDA has explained:

> FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if the compounded drug product contains the same APIs as two or more commercially available drug products in the same, similar, or easily substitutable strength and if the commercially available drug products can be used (regardless of how they are labeled) by the same route of administration prescribed for the compounded drug, unless there is documentation as described in [S]ection III.B.2.[4]

(See above reference to compounding for an individualized patient.)

The Bottom Line:

Compounding a commercially available product is permissible only in certain narrow circumstances, as described above.

The Board is charged with protecting the public. Therefore, compounding semaglutide or tirzepatide drug products in a way that fails to align with to governing law may lead to enforcement action by FDA and the Board.

Pharmacies should also be aware that pharmaceutical manufacturers may initiate legal proceedings against prescribers and compounders to combat illegal semaglutide or tirzepatide drug product compounding.

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2 FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize. U.S. Food and Drug Administration. https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

3 U.S. Food and Drug Administration. FDA Drug Shortages. FDA. https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

4 U.S. Food and Drug Administration. *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry*. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compounded-drug-products-are-essentially-copies-commercially-available-drug-product-under-section. Published December 2016. pp. 8-9.

Kentucky PDMP Reporting Reminder From OIG

Reporting to the state Prescription Drug Monitoring Program (PDMP) is outlined in the Kentucky statutes, partly in KRS 218A.202 (b):

> Every practitioner or pharmacy which dispenses a controlled substance to a person in Kentucky, or to a person at an address in Kentucky, shall report to the cabinet the data required by this section, which includes the reporting of any Schedule II controlled substance dispensed at a facility licensed by the cabinet and a Schedule II through Schedule V controlled substance regardless of dosage when dispensed by the emergency department of a hospital to an emergency department patient. Reporting shall not be required for:
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> 1. A drug administered directly to a patient in a hospital, a resident of a health care facility licensed under KRS Chapter 216B, a resident of a child-caring facility as defined by KRS 199.011, or an individual in a jail, correctional facility, or juvenile detention facility . . . .

Good clinical decisions come from having as much information as possible when making such decisions. Access to prescription data is a critical tool in that process. This information allows for reviewing possible drug interactions and drug-seeking behaviors that can be intervened upon and increase the overall quality of care. Doing your part in submitting accurate and timely prescription information to the PDMP is vital to maintaining the integrity of the data and supporting good clinical decisions.

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