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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 June 30, 2023. The renewal fees are: $125 – pharmacy and medical gas permits; $200 –3PL license; and $250 – outsourcer facility license. You may renew your permit/license online at *www.pharmacy.ky.gov.* To begin the renewal process, you must have your Kentucky permit/license number and your five-digit postal code. Resident pharmacies must verify or provide a complete listing of all licensed or registered employees. Renewal applications may be printed from the Kentucky Board of Pharmacy website. Permit/license renewals must be received in the Board office by close of business on June 30, 2023 (not postmarked). All online renewals must be completed **before** 12:01 AM (EDT) July 1, 2023. All renewals received after June 30, 2023, will be assessed a delinquent fee.

2023 CE Update

For licensing years 2023 through 2028, there is a continuing education (CE) requirement for pharmacists to complete one of the 15 contact hours on the opioid epidemic or opioid use disorder (OUD). To determine if a course meets this requirement, check the Accreditation Council for Pharmacy Education (ACPE) designation number for the course. They use a standardized number system that can be viewed here: ACPE Designations (*ashp.org*). For example, a course number will have this format: 0204-0000-20-001-L08-P. Any course that uses a Topic Number of 08 will meet the regulatory requirement for opioid epidemic or OUD.

If a course is not ACPE accredited, or if the Topic Number is not 08,

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and you believe that the course meets this new requirement, then you will need to complete the Application for Pharmacist CE Approval.

Any pharmacist requesting approval of individually obtained continuing pharmacy education shall submit the Application for Pharmacist CE Approval to the Board within 30 days of completion of the educational presentation. The Board will notify the requesting pharmacist whether the application has been approved or denied. CE that has not been accredited by ACPE or approved by the Board shall not be used to meet CE requirements for renewal or issuance of a license.

Providers who sponsor a CE program shall submit the Application for Provider CE Approval to obtain authorization for the course 60 days preceding through 30 days following presentation for approval. Pharmacists attending the Board-approved program are still required to submit the Application for Pharmacist CE Approval to obtain CE credit.

It is highly recommended that each pharmacist reviews their National Association of Boards of Pharmacy® e-Profile® transcript to ensure compliance with this CE requirement by December 31.

Reminder: Pharmacy Requirements Under DSCSA

The Drug Supply Chain Security Act (DSCSA) was federally enacted in 2013 to protect patients from potentially counterfeit prescription medications. The law addresses the distribution of most prescription drugs from the manufacturer to the dispenser (ie, the pharmacy). The DSCSA requires pharmacies to do three things:

- **Confirm that your trading partners are appropriately licensed or registered**
  Manufacturers and repackagers are required to register with Food and Drug Administration (FDA). 3PLs and wholesale distributors currently report state licensure to FDA. Pharmacists can verify this information on FDA's website. The Board requires licensure and registration for wholesale distributors and 3PLs operating within the state or shipping into Kentucky. Pharmacists can verify this information on the Board's website. Keep in mind that the Board's website lists the names of entities' parent companies, which may differ from the names that companies "do business as."
- **Receive and maintain product tracing documentation**
  With each shipment of prescription drugs, the pharmacy must receive transaction documentation, including transaction information, transaction history, and a transaction statement. This information may be received electronically or by paper. The pharmacy must maintain this documentation for six years.
- **Identify, investigate, and report suspect and illegitimate drugs**
  Pharmacies must be able to identify, quarantine, and investigate suspect prescription drugs to determine if the drugs are illegitimate. If they are illegitimate, the pharmacy must then report this to the wholesaler, manufacturer, and FDA.

Pharmacies should exercise extra vigilance in situations where there is a higher risk of suspect drugs entering the supply chain. Examples of high-risk scenarios include:

- Drugs being sold for "too good to be true" prices.
- Drugs in high demand due to drug shortages or public health emergencies.
- Drugs that have historically been counterfeited or diverted (eg, HIV drugs, antipsychotics, and cancer drugs).
- Purchases from first-time or unknown suppliers, especially if done over the internet. Pharmacies should be wary of sources that send unsolicited sales offers.
- Products that arrive with missing or incomplete information, such as incomplete shipping information or missing package inserts, lot numbers, expiration dates, or National Drug Codes.
- Products that are abnormal in appearance. This may include smudged or misspelled labels, unusual coloration or shape of the package, missing security features, or dosage forms that are different in color, shape, or imprint from the normal product.

For more information on the DSCSA and pharmacies' responsibilities, visit FDA's website. The website also includes more information on pharmacies' responsibilities when selling drugs to prescribers or other pharmacies.

Useful Links

- Wholesale Distributors and Third-Party Logistics Providers Reporting (FDA database)
- Kentucky Board of Pharmacy License Verification System
- FDA DSCSA Law and Policies Web Page
- FDA DSCSA Implementation: Identification of Suspect Product and Notification Guidance for Industry

Semaglutide Compounding Guidance

Board staff has received inquiries concerning compounding of semaglutide. Semaglutide is, of course, a commercially available drug product marketed as Ozempic® for treatment of diabetes and as Wegovy® for weight loss.

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

When Is Compounding of Semaglutide Permissible?

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

The FD&C Act also 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 (FD&C Act §503A(b)(2)). 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 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.

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act at pp. 8-9.

If/When Compounding of Semaglutide Is Permissible, How Must it Be Performed?

If and when compounding of a semaglutide drug product is allowed under the terms of the FD&C Act, pharmacists should be aware that 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 the US Department of Health and Human Services (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 (FD&C Act §503A(b)(1)(A)(i)).

With respect to semaglutide:

(1) There is no USP or NF monograph for semaglutide.
(2) Ozempic and Wegovy contain semaglutide base. Hence, only the base is a component of an FDA-approved drug. No salt form of semaglutide is contained in an FDA-approved drug.
(3) Semaglutide does not – in any form – appear on 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 obtained semaglutide base for potential compounding use, the pharmacy must ensure that the active pharmaceutical ingredient (API) received is a pharmaceutical grade product, accompanied by a valid certificate of analysis, and is sourced from an establishment registered with FDA under Section 510 of the FD&C Act (FD&C Act §503A(b)(1)(A)(ii)–(iii)). Board staff is aware that some "wholesalers" are offering "research use only" products and/or products produced by establishments not registered with FDA. These may not be used for compounding in any circumstance.

The Bottom Line

Compounding of a commercially available product is allowable only in certain narrow circumstances described above. 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.

Compounding semaglutide drug product in a way that fails to conform with governing law may lead to enforcement action by FDA and/or the Board.

Pharmacies should be aware that pharmaceutical manufacturers may choose to initiate their own legal proceedings against prescribers and compounders to combat illegal semaglutide drug product compounding.

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