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OPINION AND DECLARATORY RULING:

Guidance for Kentucky Pharmacies Acquiring Human Compounded Products from 503B Outsourcing Facilities

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This guidance document was developed from applicable state and federal laws, regulations, and policies. The Board of Pharmacy is authorized to issue Opinion and Declaratory Judgments pursuant to KRS 13A.130(3) and 13A.010(2)(b). A declaratory ruling does not create a new law or modify an existing one. Board of Pharmacy declaratory rulings are not binding, and are only offered as a guideline to licensees, permit-holders and registrants who wish to engage in a safe practice of pharmacy that promotes, preserves and protects public health, safety and welfare of the citizens of the Commonwealth.

Compounded drug products obtained from outsourcing facilities are not FDA approved nor regulated in the same manner as commercially available prescription drugs. This guidance is specific to the procurement and dispensing of compounded human drug products obtained from a Kentucky licensed outsourcing facility by a pharmacy located and permitted in Kentucky.

1. The Kentucky Board of Pharmacy expects pharmacies to conduct due diligence before purchasing from an outsourcing facility. Due diligence should include license and registration verifications. The Kentucky Board of Pharmacy recommends pharmacies review any regulatory history with the FDA (e.g. FDA-483 and warning letters):

   Complete a license verification with the Kentucky Board of Pharmacy*: https://secure2.kentucky.gov/pharmacy/licenselookup/

   **The Board's website lists the names of entities' parent companies, which may differ from the names that companies "do business as."*

   Complete a registration verification with the FDA: https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities

2. The Kentucky Board of Pharmacy expects that pharmacies only procure compounded products from outsourcing facilities in which the outsourcing facility is legally authorized to compound and in which the pharmacist is legally authorized to dispense in Kentucky.

   When compounding, outsourcing facilities may only use bulk drug substances that:

   - Are used to compound drug products that appear on FDA's drug shortage list at the time of compounding, distribution, and dispensing; or
   - Appear on the 503B Bulks List or category 1 of the Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act.

Pharmacies permitted by the Kentucky Board of Pharmacy, are required to follow 201 KAR 2:076, which states:

Non-sterile and sterile preparations compounded for human use shall:
(a)

1. Comply with the standards of an applicable USP or National Formulary monograph;
2. Be compounded from a component of a human drug approved by the United States Food and Drug Administration (FDA); or
3. Be compounded from a component that appears on the FDA's list of bulk drug substances established in 21 C.F.R. 216.23 that can be used in compounding; and

(b) Not be essential copies of a commercially available drug product unless authorized by 21 U.S.C. 353(a).

503A Bulks List

503B Bulks List

category 1 of the Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA Shortage List

3. The Kentucky Board of Pharmacy expects the outsourcing facility provide pharmacies only final finished compounded products. Any further compounding (as defined in KRS 315.010) to the final compounded product, except for products being administered in an acute care setting by a healthcare provider or the application of a patient-specific label, may be considered adulterated under KRS 315.055.

4. For current good manufacturing practice (CGMP) compliance, finished products compounded by the outsourcing facility must be tested to determine whether they meet final product specifications before their release for distribution. The Kentucky Board of Pharmacy recommends that pharmacies obtain and review the drug product release data from the outsourcing facility to ensure drug product quality testing was performed.

   Current Good Manufacturing Practices - Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act Guidance for Industry

5. The Kentucky Board of Pharmacy expects that pharmacies and pharmacists comply with the provisions of 201 KAR 2:076. 201 KAR 2:076 addresses compounding policy and procedures, standards, dispensing and labeling, and recordkeeping. No compounded drug product may be resold, transferred, or redistributed unless authorized under state or federal law.

6. Outsourcing facilities are required to report adverse events to the FDA. If a patient reports an adverse event related to a 503B compounded product to the dispensing pharmacy, the Kentucky Board of Pharmacy expects the pharmacist to refer the patient to the outsourcing facility or report to the outsourcing facility on behalf of the patient.

7. The Kentucky Board of Pharmacy expects pharmacists report any product quality concerns directly to the outsourcing facility. The outsourcing facility must handle complaints in accordance with CGMP.

8. The Kentucky Board of Pharmacy expects pharmacies to adhere to 201 KAR 2:190 regarding the reuse or resale of prescription drugs. Pharmacies may use a returns processor or waste disposal company pursuant to pharmacy policies and procedures. For any recalled product, the pharmacy should follow the procedures provided by the outsourcing facility.

APPLICABLE LAW

KRS 315.010(16) defines an Outsourcing Facility to mean a facility at one (1) geographic location or address that:
(a) Is engaged in the compounding of human sterile drugs without a patient specific prescription;
(b) Has registered as an outsourcing facility with the secretary of the United States Department of Health and Human Services, Food and Drug Administration; and
(c) Complies with all applicable state and federal requirements.

KRS 315.340 and KRS 315.342

201 KAR 2:076

201 KAR 2:190

Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b)

Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Current Good Manufacturing Practices - Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act Guidance for Industry

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry

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