A bill to be entitled

An act relating to active pharmaceutical ingredients; creating s. 465.1903, F.S.; defining the term "bulk drug substance" or "active pharmaceutical ingredient"; authorizing the sale, transfer, and distribution of certain compounded drugs under certain circumstances; providing requirements for the sale, transfer, and distribution of such medications; providing penalties; providing penalties; requiring certain persons or entities to maintain certain records for a specified timeframe and furnish such records to the Board of Pharmacy under certain circumstances within a specified timeframe; authorizing the Board of Pharmacy to conduct inspections and adopt rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

**Section 1. Section 465.1903, Florida Statutes, is created to read:**

465.1903 Active pharmaceutical ingredients.—

(1) As used in this section, the term "bulk drug substance" or "active pharmaceutical ingredient (API)" means any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity

or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. The term does not include intermediates used in the synthesis of the substance.

(2) A person or entity may only engage in the sale, transfer, or distribution of a drug compounded under s. 503A of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 353a, if the compounder of the drug uses a bulk drug substance that:

(a)1. Complies with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding.

2. If such a monograph does not exist, is a bulk drug substance that is a component of drugs approved by the United States Food and Drug Administration (FDA); or

3. If such a monograph does not exist and the bulk drug substance is not a component of a drug approved by the FDA, that appears on the list developed by the FDA pursuant to s. 503A of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 353a(b)(1)(A)(i)(III).

(b) Confirms that any bulk drug substance used under subparagraph (a)2. was reviewed as part of a new drug application approved by the FDA under s. 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 355.

(c) Ensures that the bulk drug substance is a

pharmaceutical grade product.

(d) Verifies that the bulk drug substance is accompanied by a valid certificate of analysis containing information material to the safety and effectiveness of the drug compounded using the bulk drug substance, including the identity and content of the bulk drug substance, the country where the bulk drug substance was originally manufactured, identification of each impurity by chemical name and amount present, and any additional element that the board may by regulation require.

(e) Conducts and documents quality control testing of the bulk drug substance before its use in a compounded drug to confirm:

1. The identity and content of the bulk drug substance.

2. That impurities present are identified, characterized, quantified, and justified given the product and its intended use.

(f) Obtains proof that the manufacturing of the bulk drug substance took place in a facility that:

1. Is registered with the FDA under s. 510 of the Federal Food, Drug, and Cosmetic Act.

2. Has undergone an inspection by the FDA as a human drug establishment within the previous 2 years, and such inspection:

a. Included current good manufacturing practice compliance and covered the relevant API.

b. Was classified as Voluntary Action Indicated or No

Action Indicated by the FDA.

(g) Complies with the Federal Food, Drug, and Cosmetic Act, including the provisions in s. 503A, 21 U.S.C. s. 353a.

(3) A person or entity that violates this section shall be subject to:

(a) A fine of $1,000 per dose of the illegally compounded drug sold, transferred, or distributed.

(b) Revocation of the pharmacy or facility license, as applicable.

(4) Any person or entity engaging in the sale, transfer, or distribution of compounded drugs shall maintain all records related to the acquisition, examination, and testing of the bulk drug substance for at least 2 years after the expiration date of the last lot of the drug containing the bulk drug substance and, upon request by the board, shall furnish such records within 1 business day of receiving the request, or within a reasonable time as determined by the board based on the circumstances of the request.

(5) The board or its duly authorized agent, or a duly authorized agent of a third party approved by the board, may inspect any person or entity that engages in compounding drugs, as well as any domestic supplier, wholesaler, repackager, or other provider of the bulk drug substance for compounding, for compliance with the requirements in subsection (2). Refusal to permit the board or its duly authorized agent or third-party

access to conduct an inspection shall constitute a violation of this section.

(6) The board may adopt rules and conduct inspections as necessary to implement this section.

**Section 2.** This act shall take effect upon becoming a law.