# PROPOSED AMENDMENT

## SB 282 # 9

DIGEST

Compounding. Removes a definition of adverse event and adds a definition of wholesale drug distributor. Specifies that the compounding chapter applies to a glucagon-like-peptide-1 substance used for weight management. Modifies the definitions of: (1) bulk drug substance; and (2) compounding. Exempts: (1) hospitals and ambulatory outpatient surgical centers; (2) Category II pharmacies; (3) compounding of a drug for animal use; and (4) compounding of the specified drug for a specific individual under certain circumstances; from the compounding limitations in the bill. Amends the language concerning bulk drug substance information in a certificate of analysis.

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Page 1, delete lines 1 through 4.

Page 2, between lines 2 and 3, begin a new paragraph and insert:

"SECTION 4. IC 16-18-2-373.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2026]: **Sec. 373.5. "Wholesale drug distributor", for purposes of IC 16-42-22.5, has the meaning set forth in IC 16-42-22.5-5.**".

Page 2, line 6, after "on" insert "**Certain**".

Page 2, delete lines 7 through 42, begin a new paragraph and insert:

"**Sec. 1. (a) This chapter applies to compounding concerning a glucagon-like-peptide-1 substance used for weight management.**

**(b) This chapter does not apply to the following:**

**(1) An entity licensed under IC 16-21.**

**(2) A pharmacy regulated by the board that holds a Category II permit as set forth in IC 25-26-13-17.**

**(3) The compounding of the drug for animal use.**

**(4) The compounding of the drug described in subsection (a) for a specific individual due to an allergy or required dosage specification.**

**Sec. 2. (a) As used in this chapter, "bulk drug substance" has the meaning set forth in 21 CFR 207.3 for the drug specified in section 1(a) of this chapter.**

**(b) The term does not include inactive ingredients, including**

**flavoring agents.**

**Sec. 3. (a) As used in this chapter, "bulk drug substance manufacturing establishment" means a facility that originally created the bulk drug substance through chemical, physical, biological, or other procedures or manipulations.**

**(b) The term does not include a wholesaler, relabeler, repacker, or similar entity.**

**Sec. 4. (a) As used in this chapter, "compounding" means the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a compounded preparation.**

**(b) The term does not include the mixing, reconstituting, or other acts that are performed in accordance with the directions contained in the labeling approved by the federal Food and Drug Administration provided by the product's manufacturer and other manufacturer directions consistent with the labeling.**

**Sec. 5. As used in this chapter, "wholesale drug distributor" has the meaning set forth in IC 25-26-14-12.**

**Sec. 6. (a) A person may not engage in compounding for human use under 21 U.S.C. 353a unless the following requirements are met:**

**(1) The bulk drug substance used may be used in compounding under 21 U.S.C. 353a(b)(1).**

**(2) Any bulk drug substance used under 21 U.S.C. 353a(b)(1)(A)(i)(II) has been reviewed as part of a new drug application that has been approved by the federal Food and Drug Administration under 21 U.S.C. 355.**

**(3) The bulk drug substance is a pharmaceutical grade product for human use.**

**(4) The bulk drug substance is accompanied by a valid certificate of analysis that includes any information that the board requires through the adoption of rules under IC 4-22-2.**

**(5) Either of the following requirements for documentation of quality control testing before use of the bulk drug substance in a compounded drug:**

**(A) A person engaged in compounding conducts and documents, or obtains documentation of, quality control testing of any bulk drug substance not used under 21 U.S.C. 353a(b)(1)(A)(i)(I) that includes the following:**

**(i) Confirming the identity of the bulk drug substance.**

**(ii) Reporting, identifying, characterizing, and quantifying each impurity present in the bulk drug substance in an amount exceeding one-tenth percent (0.1%).**

**(iii) Meeting any requirements of the board set forth through the adoption of rules under IC 4-22-2.**

**(B) The certificate of analysis contains the information set forth in clause (A)(i) through (A)(iii).**

**(6) The bulk drug substance is accompanied with written verification that the bulk drug substance was manufactured at a bulk drug substance manufacturing establishment that:**

**(A) is registered as a human drug establishment with the federal Food and Drug Administration under 21 U.S.C. 360;**

**(B) has been inspected by the federal Food and Drug Administration as a human drug establishment;**

**(C) is not currently subject to an federal Food and Drug Administration Import Alert; and**

**(D) is not currently subject to:**

**(i) an unresolved federal Food and Drug Administration Warning Letter; or**

**(ii) federal Food and Drug Administration inspection that is classified as Official Action Indicated.**

**The verification under this subdivision must include the country in which the bulk drug substance manufacturing establishment is located.**

**(7) The compounding complies with the federal Food, Drug, and Cosmetic Act an all other applicable requirements under Indiana law.**

**(b) Any person engaging in the sale, transfer, or distribution of compounded drugs shall do the following:**

**(1) Maintain all records related to the acquisition, examination, and testing of the bulk drug substance for at least two (2) years after the expiration date of the last lot of drug containing the bulk drug substance.**

**(2) Furnish, upon request by the board, the records described in subdivision (1) not later than one (1) business day after receipt of the request unless a reasonable alternative time frame is indicated by the board based on the circumstances of the request.**

**(c) Upon the request of the Indiana board of pharmacy during an inspection or as part of the review of a license application for records described in subsection (b), a person that engages in compounding shall provide the records to the board not later than either:**

**(1) one (1) business day after receipt of the request; or**

**(2) within a reasonable time, as determined by the Indiana board of pharmacy given the circumstances of the request.**

**(d) A wholesale drug distributor distributing bulk drug substances in Indiana for use in compounding shall provide to the purchaser of a bulk drug substance with the following:**

**(1) The valid certificate of analysis described in subsection (a)(4).**

**(2) The documentation of quality control testing described in subsection (a)(5), if the testing is not conducted by the purchaser of the bulk drug substance.**

**(3) The written verification set forth in subsection (a)(6).**

**Sec. 7. (a) The state department, in consultation with the Indiana board of pharmacy, the medical licensing board of Indiana, the Indiana state board of nursing, and the office of the attorney general shall develop and publish a report not later than November 15 of each year concerning the oversight of drug compounding during the preceding fiscal year.**

**(b) The report must include the following:**

**(1) A general assessment of the public health impact drug compounding, including the benefits and risks presented by compounding.**

**(2) The following data and information from the preceding fiscal year:**

**(A) The number and type of professional licenses issued, by license type, under which the license holder may engage in drug compounding, and whether any of the licenses issued include sterile compounding.**

**(B) The number of licensed facilities and practices that have been inspected in the previous year and the previous three (3) years, categorized by license type.**

**(C) The number of inspections conducted on a licensed facility or practice that:**

**(i) conducts drug compounding; or**

**(ii) handles, stores, administers, dispenses, distributes, or**

**uses compounded drugs in a retail or outpatient setting, including a 503A pharmacy (as described in 21 U.S.C. 353a), a 503B outsourcing facility (as described in 21 U.S.C. 353b), and a medical spa under IC 25-22.5-12.5.**

**(D) The nature and severity of any deficiency or violation found by the regulating board in an investigation of a person or facility specified in this subsection.**

**(E) The number of investigations conducted concerning drug compounding.**

**(F) The number and type of disciplinary actions taken by each board that related to drug compounding.**

**(G) The number and type of disciplinary actions taken by each board or state agency concerning the improper marketing, advertising, or promotion of compounding drugs or related services.**

**(H) An assessment of the staffing and resources of each regulating board concerning compounding drugs.**

**(c) The report required by this section must be posted on the state department's website and the Indiana board of pharmacy's website. The state department shall submit the report to the legislative council in an electronic format under IC 5-14-6.**

**(d) This section expires December 31, 2030.**".

Delete pages 3 through 4.

Page 5, delete lines 1 through 30.

Renumber all SECTIONS consecutively.

(Reference is to SB 282 as introduced.)