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# SENATE BILL No. 282

Proposed Changes to introduced printing by AM028209

DIGEST OF PROPOSED AMENDMENT

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.

A BILL FOR AN ACT to amend the Indiana Code concerning health.

*Be it enacted by the General Assembly of the State of Indiana:*

SECTION 1. IC 16-18-2-<~~7~~>[41].<~~5~~>[2] IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2026]: **Sec. <~~7~~>[41].<~~5~~>[2]. "<~~Adverse event~~>[Bulk drug substance]", for purposes of IC 16-42-22.5, has the meaning set forth in IC 16-42-22.5-<~~1~~>[2].**

SECTION 2. IC 16-18-2-41.<~~2~~>[3] IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2026]: **Sec. 41.<~~2~~>[3]. "Bulk drug substance[ manufacturing establishment]", for purposes of IC 16-42-22.5, has the meaning set forth in IC 16-42-22.5-<~~2~~>[3].**

SECTION 3. IC 16-18-2-<~~41~~>[66].<~~3~~>[8] IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2026]: **Sec. <~~41~~>[66].<~~3~~>[8]. "<~~Bulk drug substance manufacturing establishment~~>[Compounding]", for purposes of IC 16-42-22.5, has the meaning set forth in**

**IC 16-42-22.5-~~<3>~~[4].**

SECTION 4. ~~<IC 16-18-2-66>~~[IC 16-18-2-373].~~<8>~~[5] IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2026]: **Sec. ~~<66>~~[373].~~<8>~~[5]. "~~<Compounding>~~[Wholesale drug distributor]", for purposes of IC 16-42-22.5, has the meaning set forth in IC 16-42-22.5-~~<4>~~[5].**

SECTION 5. IC 16-42-22.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2026]:

**Chapter 22.5. Drugs: Restrictions on [Certain ]Bulk Drug Substances**

**Sec. 1. ~~<As used in t>~~[(a) T]his chapter~~<, "adverse event" means any untoward medical occurrence associated with the use of a prescription medication, whether or not considered prescription medication related>~~[ 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" ~~<means a substance that is intended:~~**

**~~(1) for incorporation into a finished drug product; and~~**

**~~(2) 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>~~[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 ~~<intermediates used in the synthesis of a substance>~~[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 ~~<by:~~**

~~**(1) a pharmacist licensed under IC 25-26;**~~

~~**(2) a physician licensed under IC 25-22.5; or**~~

~~**(3) an individual under the supervision of an individual described in subdivision (1) or (2), for purposes of an outsourcing facility;**~~

~~**to create a drug.**~~

~~**Sec. 5>**~~**[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 ~~<either:~~**

~~**(A) if a monograph exists, complies with the standards of the United States Pharmacopoeia or National Formulary monograph and the United States Pharmacopoeia chapter on pharmacy compounding; or**~~

~~**(B) if a monograph does not exist, is a drug substance that either:**~~

~~**(i) is a component of drugs approved by the federal Food and Drug Administration; or**~~

~~**(ii) appears on the list developed by the federal Food and Drug Administration>**~~**[may be used in compounding] under 21 U.S.C. 353a(b)(1~~~~<)(A)(i)(III>~~~~).**

**(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 ~~<and>~~[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 ~~<containing all information material to the safety and effectiveness of the drug compounding~~**

~~using>~~[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~~<, including>~~[ 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:

[ ](~~<A>~~[i]) ~~<I>~~[Confirming t]he identity~~< and content>~~ of the bulk drug substance.

[ ] (~~<B) The country where>~~[ii) Reporting, identifying, characterizing, and quantifying each impurity present in] the bulk drug substance ~~<was originally manufactured.~~

~~(C) The identification of each impurity by chemical name and amount present.~~

~~(D) Any additional information that the board requires>~~[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.

~~<(5) The bulk drug substance has had quality control testing before the bulk drug substance's use in a compounded drug that confirms the following:~~

~~(A) The identity and content of the bulk drug substance.~~

~~(B) The:~~

~~(i) identification;~~

~~(ii) characterization;~~

~~(iii) quantifying; and~~

~~(iv) justification;~~

~~of any impurities present in the bulk drug substance, given the product and the product's intended use>~~[(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;~~< and >~~

(B) has ~~< undergone an inspection in the last two (2) years >~~[been inspected] by the federal Food and Drug Administration as a human drug establishment~~< under 21 U.S.C. 374, and the inspection:~~

~~(i) verified current good manufacturing practices for >~~[;

(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 ~~< used in the compounding; and~~

~~(ii) resulted in a classification of voluntary action indicated or no action indicated >~~[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. ~~6~~[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 ~~March 1 and September~~[November] 1[5] of each year concerning the oversight of drug compounding ~~and the risks posed by~~[during] the ~~practice of compounding~~[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 ~~six (6) months~~[fiscal year]:

[ ](~~1~~[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.

[ ](~~2~~[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.

[ ](~~3~~[C]) The number of inspections conducted on a licensed facility or practice that:

[ ](~~A~~[i]) conducts drug compounding; or

[ ](~~B~~[ii]) handles, stores, administers, dispenses, distributes, or uses compounded drugs in a retail or outpatient setting, including ~~any of the following:~~

~~(i) A~~[a] 503A pharmacy (as described in 21 U.S.C. 353a)~~;~~

~~(ii) A~~[, a] 503B outsourcing facility (as described in 21 U.S.C. 353b)~~;~~

~~(iii) A~~[, and a] medical spa under ~~IC 25-26-13.7.~~

~~This clause does not apply to a hospital or an ambulatory outpatient surgical center licensed under IC 16-21.~~

~~(4>~~[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.

[ ](~~<5>~~[E]) The number of investigations conducted concerning drug compounding.

[ ](~~<6>~~[F]) The number and type of disciplinary actions taken by each board that related to drug compounding.

[ ](~~<7>~~[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 ~~<telehealth (as defined in IC 25-1-9.5-6)>~~[related] services.

[ ](~~<8>~~[H]) An assessment of the staffing and resources of each regulating board concerning compounding~~<drugs given the high risk posed by the practice.~~

~~(9) An analysis of the nature and severity of the emerging high risk that involve the compounding of drugs as well as the distribution, marketing, and the sale of compounded>~~ 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.

] SECTION 6. IC 25-26-13.7 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2026]:

Chapter 13.7. Medical Spas

Sec. 1. (a) As used in this chapter, "medical spa" means a facility or practice that:

(1) offers or provides medical health care services;

(2) engages in the preparation, administration, or dispensing of prescription drugs or otherwise uses prescription drugs for intravenous, intramuscular, or subcutaneous delivery; and

(3) holds itself out as a facility or practice focused on cosmetic or lifestyle treatments, including any of the

**following:**

**(A) Weight loss.**

**(B) Wellness.**

**(C) Longevity.**

**(D) Cosmetic or aesthetic health service, including the preparation, administration, or dispensing of prescription drugs for:**

**(i) weight loss;**

**(ii) botulinum toxin injections;**

**(iii) hormone therapies; or**

**(iv) parenteral nutrient therapies.**

**(b) The term does not apply to a facility or practice that is otherwise licensed by the state.**

**Sec. 2. (a) Beginning January 1, 2027, a medical spa is required to be registered under this chapter in order to do business in Indiana.**

**(b) The board shall establish a registration procedure for medical spas for implementation not later than January 1, 2027. An application for registration for a medical spa must include the following:**

**(1) The name of the medical spa.**

**(2) The address of the medical spa.**

**(3) The medical spa's license number.**

**(4) The name and license number of the medical spa's licensed responsible person as described in section 4 of this chapter.**

**(c) The board may fine a person that operates an unregistered medical spa and require that the person obtain registration under this chapter in order to do business in Indiana.**

**Sec. 3. (a) The board shall establish and maintain a public data base that contains:**

**(1) the information specified in section 2(b) of this chapter for each registered medical spa; and**

**(2) any disciplinary action taken by the board for a violation of this chapter.**

**(b) The board shall redact any personally identifying health information as confidential before including any information on the data base.**

**Sec. 4. (a) A medical spa registered under this chapter must designate a responsible person. The board may require a medical spa to receive the board's approval before a medical spa may designate a responsible person to be in charge of more than one (1)**

**location.**

**(b) A responsible person shall be physically present at the medical spa location for a sufficient amount of time to comply with the responsibility of ensuring that the medical spa complies with the requirements of this chapter.**

**Sec. 5. (a) As used in this section, "serious adverse event" means any negative medical occurrence associated with the use of a prescription medication that results in, based on a reasonable medical judgment, jeopardy to an individual's health resulting in medical or surgical intervention or any of the following outcomes:**

**(1) Death.**

**(2) A life threatening medical occurrence.**

**(3) Inpatient hospitalization or prolonging of an existing hospitalization.**

**(4) Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.**

**(5) Congenital anomaly or birth defect.**

**(b) A medical spa shall notify the board in the manner prescribed by the board not later than five (5) days after the occurrence of a patient's serious adverse event. The notice must include, to the extent that the information may be obtained or reasonably available from the source, the following:**

**(1) The name of the patient, the prescription medication involved, and the date of the serious adverse event.**

**(2) The nature and location of the serious adverse event.**

**(3) The medical records for the patient concerning the serious adverse event.**

**Sec. 6. (a) The board, or a person contracting with the board, may inspect a medical spa that:**

**(1) has applied for registration; or**

**(2) is registered;**

**under this chapter. A person that denies access to the facility for an inspection violates this chapter.**

**(b) The board shall investigate any claim of a violation of this chapter and take any necessary enforcement action.**

**Sec. 7. (a) The board may take disciplinary action under IC 25-1-9 against a medical spa registered under this chapter for failure to comply with this chapter or IC 16-42-22.5.**

**(b) The board may suspend a registration under this chapter if the medical spa poses a danger to the public.**

**Sec. 8. The board may adopt rules under IC 4-22-2 that are necessary to implement this chapter.[**

1 ]