

SENATE BILL No. 282

DIGEST OF INTRODUCED BILL

Citations Affected: IC 16-18-2; IC 16-42-22.5; IC 25-26-13.7.

Synopsis: Compounding drugs and medical spas. Restricts compounding of drugs using bulk drug substances unless certain requirements are met. Requires persons selling, transferring, or distributing compounded drugs to maintain specified records. Requires the Indiana department of health to prepare a report concerning the oversight of drug compounding and the posed risks of compounding. Beginning January 1, 2027, requires the registration of medical spas under the Indiana board of pharmacy (board). Requires the board to establish and maintain a public data base concerning registered medical spas. Requires a medical spa to designate a responsible person that is physically present for a sufficient time to ensure compliance with requirements as part of registration. Requires a medical spa to notify the board after a serious adverse event. Allows the board to take disciplinary action, including the suspension of a medical spa registration.

Effective: July 1, 2026.

Charbonneau

January 12, 2026, read first time and referred to Committee on Health and Provider Services.



Introduced

Second Regular Session of the 124th General Assembly (2026)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2025 Regular Session of the General Assembly.

SENATE BILL No. 282

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

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

1 SECTION 1. IC 16-18-2-7.5 IS ADDED TO THE INDIANA CODE
2 AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
3 1, 2026]: **Sec. 7.5. "Adverse event", for purposes of IC 16-42-22.5,**
4 **has the meaning set forth in IC 16-42-22.5-1.**

5 SECTION 2. IC 16-18-2-41.2 IS ADDED TO THE INDIANA
6 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
7 [EFFECTIVE JULY 1, 2026]: **Sec. 41.2. "Bulk drug substance", for**
8 **purposes of IC 16-42-22.5, has the meaning set forth in**
9 **IC 16-42-22.5-2.**

10 SECTION 3. IC 16-18-2-41.3 IS ADDED TO THE INDIANA
11 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
12 [EFFECTIVE JULY 1, 2026]: **Sec. 41.3. "Bulk drug substance**
13 **manufacturing establishment", for purposes of IC 16-42-22.5, has**
14 **the meaning set forth in IC 16-42-22.5-3.**

15 SECTION 4. IC 16-18-2-66.8 IS ADDED TO THE INDIANA
16 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
17 [EFFECTIVE JULY 1, 2026]: **Sec. 66.8. "Compounding", for**



1 purposes of IC 16-42-22.5, has the meaning set forth in
2 **IC 16-42-22.5-4.**

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

6 **Chapter 22.5. Drugs: Restrictions on Bulk Drug Substances**

7 **Sec. 1.** As used in this chapter, "adverse event" means any
8 untoward medical occurrence associated with the use of a
9 prescription medication, whether or not considered prescription
10 medication related.

11 **Sec. 2. (a)** As used in this chapter, "bulk drug substance" means
12 a substance that is intended:

13 (1) for incorporation into a finished drug product; and
14 (2) to furnish pharmacological activity or other direct effect;
15 in the diagnosis, cure, mitigation, treatment, or prevention of
16 disease, or to affect the structure or any function of the body.

17 **(b)** The term does not include intermediates used in the
18 synthesis of a substance.

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

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

25 **Sec. 4.** As used in this chapter, "compounding" means the
26 combining, admixing, mixing, diluting, pooling, reconstituting, or
27 otherwise altering of a drug or bulk drug substance by:

28 (1) a pharmacist licensed under IC 25-26;
29 (2) a physician licensed under IC 25-22.5; or
30 (3) an individual under the supervision of an individual
31 described in subdivision (1) or (2), for purposes of an
32 outsourcing facility;

33 to create a drug.

34 **Sec. 5. (a)** A person may not engage in compounding unless the
35 following requirements are met:

36 **(1) The bulk drug substance used either:**

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

41 (B) if a monograph does not exist, is a drug substance that
42 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 under 21 U.S.C. 353a(b)(1)(A)(i)(III).

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

(3) The bulk drug substance is a pharmaceutical grade product.

(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 the bulk drug substance, including the following:

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

(B) The country where 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 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.

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

(A) is registered 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 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 the



bulk drug substance used in the compounding; and
(ii) resulted in a classification of voluntary action
indicated or no action indicated.

(7) The compounding complies with the federal Food, Drug, and Cosmetic Act.

(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 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.

Sec. 6. (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 1 of each year concerning the oversight of drug compounding and the risks posed by the practice of compounding.

(b) The report must include the following data from the preceding six (6) months:

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

(A) conducts drug compounding; or



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

- (i) A 503A pharmacy (as described in 21 U.S.C. 353a).
- (ii) A 503B outsourcing facility (as described in 21 U.S.C. 353b).

(iii) 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) 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) The number of investigations conducted concerning drug compounding.

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

(7) 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) services.

(8) 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.

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:





1 **medical spa location for a sufficient amount of time to comply with**
2 **the responsibility of ensuring that the medical spa complies with**
3 **the requirements of this chapter.**

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

9 **(1) Death.**
10 **(2) A life threatening medical occurrence.**
11 **(3) Inpatient hospitalization or prolonging of an existing**
12 **hospitalization.**
13 **(4) Persistent or significant incapacity or substantial**
14 **disruption of the ability to conduct normal life functions.**
15 **(5) Congenital anomaly or birth defect.**

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

21 **(1) The name of the patient, the prescription medication**
22 **involved, and the date of the serious adverse event.**
23 **(2) The nature and location of the serious adverse event.**
24 **(3) The medical records for the patient concerning the serious**
25 **adverse event.**

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

28 **(1) has applied for registration; or**
29 **(2) is registered;**

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

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

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

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

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

