



Adopted	Rejected
---------	----------

COMMITTEE REPORT

YES:	12
NO:	0

MR. SPEAKER:

*Your Committee on Public Health, to which was referred Senate Bill 282, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill **be amended** as follows:*

- 1 Page 1, delete lines 1 through 17, begin a new paragraph and insert:
- 2 "SECTION 1. IC 16-18-2-41.2 IS ADDED TO THE INDIANA
- 3 CODE AS A **NEW SECTION** TO READ AS FOLLOWS
- 4 [EFFECTIVE JULY 1, 2026]: **Sec. 41.2. "Bulk drug substance", for**
- 5 **purposes of IC 16-42-22.5, has the meaning set forth in**
- 6 **IC 16-42-22.5-1.**
- 7 SECTION 2. IC 16-18-2-66.8 IS ADDED TO THE INDIANA
- 8 CODE AS A **NEW SECTION** TO READ AS FOLLOWS
- 9 [EFFECTIVE JULY 1, 2026]: **Sec. 66.8. "Compounding", for**
- 10 **purposes of IC 16-42-22.5, has the meaning set forth in**
- 11 **IC 16-42-22.5-2.**
- 12 SECTION 3. IC 16-42-22.5 IS ADDED TO THE INDIANA CODE
- 13 AS A **NEW CHAPTER** TO READ AS FOLLOWS [EFFECTIVE

- 1 JULY 1, 2026];
- 2 **Chapter 22.5. Drugs: Restrictions on Bulk Drug Substances**
- 3 **Sec. 0.5. This chapter does not apply to the compounding of the**
- 4 **drug for animal use.**
- 5 **Sec. 1. (a) As used in this chapter, "bulk drug substance" means**
- 6 **a substance that is intended:**
- 7 **(1) for incorporation into a finished drug product; and**
- 8 **(2) to furnish pharmacological activity or other direct effect;**
- 9 **in the diagnosis, cure, mitigation, treatment, or prevention of**
- 10 **disease, or to affect the structure or any function of the body.**
- 11 **(b) The term does not include intermediates used in the**
- 12 **synthesis of a substance.**
- 13 **Sec. 2. As used in this chapter, "compounding" means the**
- 14 **combining, admixing, mixing, diluting, pooling, or otherwise**
- 15 **altering of a drug or bulk drug substance by:**
- 16 **(1) a pharmacist licensed under IC 25-26;**
- 17 **(2) a physician licensed under IC 25-22.5; or**
- 18 **(3) an individual under the supervision of an individual**
- 19 **described in subdivision (1) or (2), for purposes of an**
- 20 **outsourcing facility;**
- 21 **to create a drug.**
- 22 **Sec. 3. (a) A person may not engage in compounding unless the**
- 23 **following requirements are met:**
- 24 **(1) The bulk drug substance:**
- 25 **(A) is not research grade or veterinary grade; and**
- 26 **(B) complies with standards of the United States**
- 27 **Pharmacopeia (USP) or National Formulary monograph**
- 28 **and any applicable United States Pharmacopoeia chapter**
- 29 **on pharmacy compounding.**
- 30 **(2) The bulk drug substance was manufactured by an**
- 31 **establishment that is registered as a human drug**
- 32 **establishment with the federal Food and Drug Administration**
- 33 **under 21 U.S.C. 360.**
- 34 **(3) The bulk drug substance is accompanied by a valid**
- 35 **certificate of analysis that includes the following:**
- 36 **(A) The identity and content of the bulk drug substance.**
- 37 **(B) The country where the bulk drug substance was**
- 38 **originally manufactured.**

- 1 **(C) Any additional information that the state department**
2 **requires through the adoption of rules under IC 4-22-2.**
- 3 **(4) The bulk drug substance has had quality control testing**
4 **conducted.**
- 5 **(5) The compounding complies with the federal Food, Drug,**
6 **and Cosmetic Act.**
- 7 **(b) Upon request by the Indiana board of pharmacy, a**
8 **nonresident pharmacy (as defined in IC 25-26-17-2) that ships,**
9 **mails, delivers, or dispenses a compounded drug into Indiana that**
10 **is compounded using a bulk drug substance shall provide**
11 **documentation demonstrating compliance with this chapter and**
12 **IC 25-26-17-3 within a reasonable time, as determined by the**
13 **Indiana board of pharmacy based on the circumstances of the**
14 **request.**
- 15 **(c) Any person engaging in the sale, transfer, or distribution of**
16 **compounding drugs shall maintain all records related to the**
17 **acquisition, examination, and testing of the bulk drug substance for**
18 **at least two (2) years after the expiration date of the last lot of**
19 **drugs containing the bulk drug substance.**
- 20 **Sec. 4. (a) A pharmacy that is subject to Section 503A of the**
21 **federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) shall**
22 **comply with Section 503A of the federal Food, Drug, and Cosmetic**
23 **Act, and any regulation promulgated under Section 503A of the**
24 **federal Food, Drug, and Cosmetic Act.**
- 25 **(b) A pharmacy that is subject to Section 503B of the federal**
26 **Food, Drug, and Cosmetic Act (21 U.S.C. 353b) shall comply with**
27 **Section 503B of the federal Food, Drug, and Cosmetic Act, and any**
28 **regulation promulgated under Section 503B of the federal Food,**
29 **Drug, and Cosmetic Act.**
- 30 **(c) A manufacturer required to obtain approval under 21 U.S.C.**
31 **355 shall comply with federal new drug approval and current good**
32 **manufacturing practice requirements.**
- 33 **Sec. 5. The Indiana board of pharmacy may investigate any**
34 **alleged violation of this chapter.**
- 35 **Sec. 6. (a) The state department, in consultation with the**
36 **Indiana board of pharmacy, the medical licensing board of**
37 **Indiana, the Indiana state board of nursing, and the office of the**
38 **attorney general shall develop and publish a report not later than**

1 **March 1 and September 1 of each year concerning the oversight of**
2 **drug compounding and the risks and benefits posed by the practice**
3 **of compounding.**

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

5 **(1) The number and type of professional licenses issued, by**
6 **license type, under which the license holder may engage in**
7 **drug compounding.**

8 **(2) The number of licensed facilities and practices that:**

9 **(A) conduct drug compounding; or**

10 **(B) handle, store, administer, dispense, distribute, or use**
11 **compounded drugs in a retail or outpatient setting,**
12 **including:**

13 **(i) a 503A pharmacy (as described in 21 U.S.C. 353a);**
14 **and**

15 **(ii) a medical spa (as defined in IC 25-22.5-12.5);**

16 **categorized by license type. This subdivision does not include**
17 **a hospital or ambulatory outpatient surgical center licensed**
18 **under IC 16-21.**

19 **(3) A summary of any findings related to deficiencies or**
20 **violations found by the regulating board for a facility**
21 **described in subdivision (2).**

22 **(4) The number of investigations conducted concerning drug**
23 **compounding.**

24 **(5) The number and type of disciplinary actions taken,**
25 **including improper marketing, advertising, or promotion of**
26 **compounding drugs or related services.**

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

31 Page 2, delete lines 1 through 17.

32 Page 2, between lines 40 and 41, begin a new line double block
33 indented and insert:

34 **"(E) The nonsurgical use of a laser or other energy device**
35 **for cosmetic purposes, including use for rejuvenation,**
36 **anti-aging, or hair removal."**

37 Page 2, line 41, delete "to a" and insert **"to the following:**

38 **(1) A physician's office.**

- 1 **(2) A".**
- 2 Page 3, line 12, delete "for implementation".
- 3 Page 3, line 12, delete "January 1, 2027." and insert "**October 1,**
- 4 **2026."**
- 5 Page 3, line 15, delete "spa." and insert "**spa, including the**
- 6 **following:**
- 7 **(A) Any name under which the medical spa does or will do**
- 8 **business in Indiana.**
- 9 **(B) The legal name of the medical spa."**
- 10 Page 3, line 17, after "(3)" insert "**The website address of the**
- 11 **medical spa.**
- 12 **(4)".**
- 13 Page 3, delete lines 19 through 21, begin a new line block indented
- 14 and insert:
- 15 **"(5) The prescription drugs that are intended to be:**
- 16 **(A) compounded (as defined in IC 16-42-22.5-2); and**
- 17 **(B) prepared, administered, dispensed, or otherwise used;**
- 18 **at the medical spa."**
- 19 Page 3, line 22, delete "(5)" and insert "**(6)".**
- 20 Page 3, line 23, delete "." and insert "**and the name of the**
- 21 **responsible practitioner's collaborating physician or supervising**
- 22 **practitioner, if applicable."**
- 23 Page 3, delete lines 24 through 25.
- 24 Page 3, line 31, delete "contains:" and insert "**contains the**
- 25 **information specified in section 3(b) of this chapter for each**
- 26 **registered medical spa."**
- 27 Page 3, delete lines 32 through 35.
- 28 Page 4, line 6, delete "The board may require a medical".
- 29 Page 4, delete lines 7 through 9.
- 30 Page 4, line 16, delete "Is properly trained" and insert "**Has**
- 31 **received appropriate training"**.
- 32 Page 4, delete lines 28 through 30.
- 33 Page 4, line 32, delete "five (5)" and insert "**fifteen (15)".**
- 34 Page 4, delete lines 41 through 42.
- 35 Page 5, delete lines 1 through 11, begin a new paragraph and insert:
- 36 **"Sec. 7. The board may investigate a responsible practitioner**
- 37 **concerning any claim of a violation of this chapter and forward**
- 38 **any substantiated claim to the governing board of the responsible**

1 **practitioner.**

2 **Sec. 8. An individual licensed or certified under this title who**
 3 **violates this chapter is subject to discipline under IC 25-1-9."**

4 Page 5, line 14, delete "office, a physician's office, or other licensed"
 5 and insert "**office unless the health care service or treatment is being**
 6 **performed in another location for educational or training purposes**
 7 **of individuals who intend to provide these services or treatment.**

8 **Sec. 10. (a) A medical spa shall comply with the advertising**
 9 **requirements set forth in IC 25-1-10.3.**

10 **(b) The board may suspend a registration under this chapter for**
 11 **a violation of IC 25-1-10.3.**

12 **Sec. 11. (a) The board shall consult with the appropriate**
 13 **professional board that has oversight of a profession concerning**
 14 **any issues concerning the practice of the profession as it relates to**
 15 **providing services in a medical spa.**

16 **(b) Nothing in this chapter precludes a governing board of a**
 17 **practitioner to take any action against a practitioner for a violation**
 18 **of the practitioner's license or certification."**

19 Page 5, delete lines 15 through 17, begin a new paragraph and
 20 insert:

21 "SECTION 5. IC 25-26-13-4, AS AMENDED BY P.L.93-2024,
 22 SECTION 186, IS AMENDED TO READ AS FOLLOWS
 23 [EFFECTIVE JULY 1, 2026]: Sec. 4. (a) The board may:

24 (1) adopt rules under IC 4-22-2 for implementing and enforcing
 25 this chapter;

26 (2) establish requirements and tests to determine the moral,
 27 physical, intellectual, educational, scientific, technical, and
 28 professional qualifications for applicants for pharmacists'
 29 licenses;

30 (3) refuse to issue, deny, suspend, or revoke a license or permit or
 31 place on probation or fine any licensee or permittee under this
 32 chapter;

33 (4) regulate the sale of drugs and devices in the state of Indiana;

34 (5) impound, embargo, confiscate, or otherwise prevent from
 35 disposition any drugs, medicines, chemicals, poisons, or devices
 36 which by inspection are deemed unfit for use or would be
 37 dangerous to the health and welfare of the citizens of the state of
 38 Indiana; the board shall follow those embargo procedures found

- 1 in IC 16-42-1-18 through IC 16-42-1-31, and persons may not
 2 refuse to permit or otherwise prevent members of the board or
 3 their representatives from entering such places and making such
 4 inspections;
- 5 (6) prescribe minimum standards with respect to physical
 6 characteristics of pharmacies, as may be necessary to the
 7 maintenance of professional surroundings and to the protection of
 8 the safety and welfare of the public;
- 9 (7) subject to IC 25-1-7, investigate complaints, subpoena
 10 witnesses, schedule and conduct hearings on behalf of the public
 11 interest on any matter under the jurisdiction of the board;
- 12 (8) prescribe the time, place, method, manner, scope, and subjects
 13 of licensing examinations which shall be given at least twice
 14 annually; ~~and~~
- 15 (9) perform such other duties and functions and exercise such
 16 other powers as may be necessary to implement and enforce this
 17 chapter; **and**
- 18 **(10) investigate any alleged violation of IC 16-42-22.5.**
- 19 (b) The board shall adopt rules under IC 4-22-2 for the following:
- 20 (1) Establishing standards for the competent practice of
 21 pharmacy.
- 22 (2) Establishing the standards for a pharmacist to counsel
 23 individuals regarding the proper use of drugs.
- 24 (3) Establishing standards and procedures before January 1, 2006,
 25 to ensure that a pharmacist:
- 26 (A) has entered into a contract that accepts the return of
 27 expired drugs with; or
- 28 (B) is subject to a policy that accepts the return of expired
 29 drugs of;
- 30 a wholesaler, manufacturer, or agent of a wholesaler or
 31 manufacturer concerning the return by the pharmacist to the
 32 wholesaler, the manufacturer, or the agent of expired legend drugs
 33 or controlled drugs. In determining the standards and procedures,
 34 the board may not interfere with negotiated terms related to cost,
 35 expenses, or reimbursement charges contained in contracts
 36 between parties, but may consider what is a reasonable quantity
 37 of a drug to be purchased by a pharmacy. The standards and
 38 procedures do not apply to vaccines that prevent influenza,

1 medicine used for the treatment of malignant hyperthermia, and
 2 other drugs determined by the board to not be subject to a return
 3 policy. An agent of a wholesaler or manufacturer must be
 4 appointed in writing and have policies, personnel, and facilities
 5 to handle properly returns of expired legend drugs and controlled
 6 substances.

7 (c) The board may grant or deny a temporary variance to a rule it
 8 has adopted if:

9 (1) the board has adopted rules which set forth the procedures and
 10 standards governing the grant or denial of a temporary variance;
 11 and

12 (2) the board sets forth in writing the reasons for a grant or denial
 13 of a temporary variance.

14 (d) The board shall adopt rules and procedures, in consultation with
 15 the medical licensing board, concerning the electronic transmission of
 16 prescriptions. The rules adopted under this subsection must address the
 17 following:

18 (1) Privacy protection for the practitioner and the practitioner's
 19 patient.

20 (2) Security of the electronic transmission.

21 (3) A process for approving electronic data intermediaries for the
 22 electronic transmission of prescriptions.

23 (4) Use of a practitioner's United States Drug Enforcement
 24 Agency registration number.

25 (5) Protection of the practitioner from identity theft or fraudulent
 26 use of the practitioner's prescribing authority.

27 (e) The governor may direct the board to develop:

28 (1) a prescription drug program that includes the establishment of
 29 criteria to eliminate or significantly reduce prescription fraud; and

30 (2) a standard format for an official tamper resistant prescription
 31 drug form for prescriptions (as defined in IC 16-42-19-7(1)).

32 The board may adopt rules under IC 4-22-2 necessary to implement
 33 this subsection.

34 (f) The standard format for a prescription drug form described in
 35 subsection (e)(2) must include the following:

36 (1) A counterfeit protection bar code with human readable
 37 representation of the data in the bar code.

38 (2) A thermochromic mark on the front and the back of the

- 1 prescription that:
- 2 (A) is at least one-fourth (1/4) of one (1) inch in height and
- 3 width; and
- 4 (B) changes from blue to clear when exposed to heat.
- 5 (g) The board may contract with a supplier to implement and
- 6 manage the prescription drug program described in subsection (e). The
- 7 supplier must:
- 8 (1) have been audited by a third party auditor using the SAS 70
- 9 audit or an equivalent audit for at least the three (3) previous
- 10 years; and
- 11 (2) be audited by a third party auditor using the SAS 70 audit or
- 12 an equivalent audit throughout the duration of the contract;
- 13 in order to be considered to implement and manage the program.
- 14 (h) The board shall adopt rules under IC 4-22-2 concerning:
- 15 (1) professional determinations made under IC 35-48-4-14.7(d);
- 16 and
- 17 (2) the determination of a relationship on record with the
- 18 pharmacy under IC 35-48-4-14.7.
- 19 (i) The board may:
- 20 (1) review professional determinations made by a pharmacist; and
- 21 (2) take appropriate disciplinary action against a pharmacist who
- 22 violates a rule adopted under subsection (h) concerning a
- 23 professional determination made;
- 24 under IC 35-48-4-14.7 concerning the sale of ephedrine and
- 25 pseudoephedrine.".
- 26 Renumber all SECTIONS consecutively.
- (Reference is to SB 282 as reprinted January 29, 2026.)

and when so amended that said bill do pass.

Representative Barrett