

PROPOSED AMENDMENT

SB 282 # 11

DIGEST

Compounding drugs; medical spas. Removes language concerning complying with specified provisions of federal law. Adds language from the introduced version of the bill with modifications. Makes changes to the registration of medical spas.

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
14 JULY 1, 2026]:
15 **Chapter 22.5. Drugs: Restrictions on Bulk Drug Substances**
16 **Sec. 1. (a) As used in this chapter, "bulk drug substance" means**
17 **a substance that is intended:**
18 **(1) for incorporation into a finished drug product; and**
19 **(2) to furnish pharmacological activity or other direct effect;**
20 **in the diagnosis, cure, mitigation, treatment, or prevention of**
21 **disease, or to affect the structure or any function of the body.**
22 **(b) The term does not include intermediates used in the**
23 **synthesis of a substance.**
24 **Sec. 2. As used in this chapter, "compounding" means the**
25 **combining, admixing, mixing, diluting, pooling, reconstituting, or**
26 **otherwise altering of a drug or bulk drug substance by:**

- 1 **(1) a pharmacist licensed under IC 25-26;**
- 2 **(2) a physician licensed under IC 25-22.5; or**
- 3 **(3) an individual under the supervision of an individual**
- 4 **described in subdivision (1) or (2), for purposes of an**
- 5 **outsourcing facility;**
- 6 **to create a drug.**

7 **Sec. 3. (a) A person may not engage in compounding unless the**

8 **following requirements are met:**

9 **(1) Any bulk drug substance used has been reviewed as part**

10 **of a new drug application and approved by the federal Food**

11 **and Drug Administration under 21 U.S.C. 355.**

12 **(2) The bulk drug substance is a pharmaceutical grade**

13 **product.**

14 **(3) The bulk drug substance is accompanied by a valid**

15 **certificate of analysis that contains all information that is**

16 **material to the safety and effectiveness of the drug**

17 **compounding using the bulk drug substance, including the**

18 **following:**

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

20 **(B) The country where the bulk drug substance was**

21 **originally manufactured.**

22 **(C) The identification of each impurity by chemical name**

23 **and the amount present.**

24 **(D) Any additional information that the state department**

25 **requires through the adoption of rules under IC 4-22-2.**

26 **(4) The bulk drug substance has had quality control testing**

27 **conducted.**

28 **(5) The compounding complies with the federal Food, Drug,**

29 **and Cosmetic Act.**

30 **(b) Upon request by the Indiana board of pharmacy, a**

31 **nonresident pharmacy (as defined in IC 25-26-17-2) that ships,**

32 **mails, delivers, or dispenses a compounded drug into Indiana that**

33 **is compounded using a bulk drug substance shall provide**

34 **documentation demonstrating compliance with this chapter within**

35 **a reasonable time, as determined by the Indiana board of**

36 **pharmacy based on the circumstances of the request.**

37 **(c) Any person engaging in the sale, transfer, or distribution of**

38 **compounding drugs shall maintain all records related to the**

39 **acquisition, examination, and testing of the bulk drug substance for**

40 **at least two (2) years after the expiration date of the last lot of drug**

1 containing the bulk drug substance.

2 Sec. 4. (a) The state department, in consultation with the
3 Indiana board of pharmacy, the medical licensing board of
4 Indiana, the Indiana state board of nursing, and the office of the
5 attorney general shall develop and publish a report not later than
6 March 1 and September 1 of each year concerning the oversight of
7 drug compounding and the risks posed by the practice of
8 compounding.

9 (b) The report must include the following:

10 (1) The number and type of professional licenses issued, by
11 license type, under which the license holder may engage in
12 drug compounding.

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

14 (A) conduct drug compounding; or

15 (B) handle, store, administer, dispense, distribute, or use
16 compounded drugs in a retail or outpatient setting,
17 including:

18 (i) a 503A pharmacy (as described in 21 U.S.C. 353a);
19 and

20 (ii) a medical spa (as defined in IC 25-26-13.7);

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

24 (3) A summary of any findings related to deficiencies or
25 violations found by the regulating board for a facility
26 described in subdivision (2).

27 (4) The number of investigations conducted concerning drug
28 compounding.

29 (5) The number and type of disciplinary actions taken,
30 including improper marketing, advertising, or promotion of
31 compounding drugs or telehealth (as defined in IC 25-1-9.5-6)
32 services.

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

37 Page 2, delete lines 1 through 17.

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

40 "(E) The nonsurgical use of a laser or other energy device

1 **for cosmetic purposes, including use for rejuvenation,**
2 **anti-aging, or hair removal."**

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

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

5 **(2) A".**

6 Page 3, line 12, delete "for implementation".

7 Page 3, line 12, delete "January 1, 2027." and insert **"October 1,**
8 **2026."**

9 Page 3, line 15, delete "spa." and insert **"spa, including the**
10 **following:**

11 **(A) Any name under which the medical spa does or will do**
12 **business in Indiana.**

13 **(B) The legal name of the medical spa."**

14 Page 3, line 17, after "(3)" insert **"The website address of the**
15 **medical spa.**

16 **(4)".**

17 Page 3, delete lines 19 through 21.

18 Page 3, line 23, delete "." and insert **"and the name of the**
19 **responsible practitioner's collaborating physician, if applicable."**

20 Page 3, delete lines 24 through 25.

21 Page 3, line 31, delete "contains:" and insert **"contains the**
22 **information specified in section 3(b) of this chapter for each**
23 **registered medical spa."**

24 Page 3, delete lines 32 through 35.

25 Page 4, line 6, delete "The board may require a medical".

26 Page 4, delete lines 7 through 9.

27 Page 4, line 16, delete "Is properly trained" and insert **"Has**
28 **received appropriate training"**.

29 Page 4, delete lines 18 through 42.

30 Page 5, delete lines 1 through 6.

31 Page 5, line 7, delete "8." and insert **"6."**

32 Page 5, line 12, delete "9." and insert **"7."**

33 Page 5, line 15, delete "." and insert **"unless the health care service**
34 **or treatment is being performed in another location for**
35 **educational or training purposes of individuals who intend to**
36 **provide these services or treatment.**

37 **Sec. 8. A medical spa shall comply with the advertising**
38 **requirements set forth in IC 25-1-10.5.**

39 **Sec. 9. The board shall consult with the appropriate professional**
40 **board that has oversight of a profession concerning any issues**

1 **concerning the practice of the profession as it relates to providing**
2 **services in a medical spa."**

3 Renumber all SECTIONS consecutively.

(Reference is to SB 282 as reprinted January 29, 2026.)