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SENATE BILL No. 282

Proposed Changes to introduced printing by AM028203

DIGEST OF PROPOSED AMENDMENT

Compounding removal; medical spas. Removes language concerning compounding limitations. Applies definitions concerning pharmacies and pharmacists to the chapter on medical spas. Amends the definition of "medical spa". Changes information that must be included in an application for registration as a medical spa. Changes references from "responsible person" to "responsible practitioner". Specifies that a responsible practitioner who has prescriptive authority must be physically present at the medical spa. Allows for the suspension of a medical spa's registration in accordance with health professions' standard of practice statute.

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~~
2 ~~CODE AS A NEW SECTION TO READ AS FOLLOWS~~
3 ~~[EFFECTIVE JULY 1, 2026]: See. 7.5. "Adverse event", for~~
4 ~~purposes of IC 16-42-22.5, has the meaning set forth in~~
5 ~~IC 16-42-22.5-1.~~
6 ~~SECTION 2. IC 16-18-2-41.2 IS ADDED TO THE INDIANA~~
7 ~~CODE AS A NEW SECTION TO READ AS FOLLOWS~~
8 ~~[EFFECTIVE JULY 1, 2026]: See. 41.2. "Bulk drug substance", for~~
9 ~~purposes of IC 16-42-22.5, has the meaning set forth in~~
10 ~~IC 16-42-22.5-2.~~
11 ~~SECTION 3. IC 16-18-2-41.3 IS ADDED TO THE INDIANA~~
12 ~~CODE AS A NEW SECTION TO READ AS FOLLOWS~~
13 ~~[EFFECTIVE JULY 1, 2026]: See. 41.3. "Bulk drug substance~~
14 ~~manufacturing establishment", for purposes of IC 16-42-22.5, has~~
15 ~~the meaning set forth in IC 16-42-22.5-3.~~

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1 ~~SECTION 4. IC 16-18-2-66.8 IS ADDED TO THE INDIANA~~
2 ~~CODE AS A NEW SECTION TO READ AS FOLLOWS~~
3 ~~[EFFECTIVE JULY 1, 2026]. See. 66.8. "Compounding", for~~
4 ~~purposes of IC 16-42-22.5, has the meaning set forth in~~
5 ~~IC 16-42-22.5-4.~~

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

9 ~~Chapter 22.5. Drugs: Restrictions on Bulk Drug Substances~~
10 ~~Sec. 1. As used in this chapter, "adverse event" means any~~
11 ~~untoward medical occurrence associated with the use of a~~
12 ~~prescription medication, whether or not considered prescription~~
13 ~~medication related.~~

14 ~~Sec. 2. (a) As used in this chapter, "bulk drug substance"~~
15 ~~means a substance that is intended:~~

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

20 ~~(b) The term does not include intermediates used in the~~
21 ~~synthesis of a substance.~~

22 ~~See. 3. (a) As used in this chapter, "bulk drug substance~~
23 ~~manufacturing establishment" means a facility that originally~~
24 ~~created the bulk drug substance through chemical, physical,~~
25 ~~biological, or other procedures or manipulations.~~

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

28 ~~Sec. 4. As used in this chapter, "compounding" means the~~
29 ~~combining, admixing, mixing, diluting, pooling, reconstituting, or~~
30 ~~otherwise altering of a drug or bulk drug substance by:~~

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

36 ~~to create a drug.~~

37 ~~Sec. 5. (a) A person may not engage in compounding unless the~~
38 ~~following requirements are met:~~

39 ~~(1) The bulk drug substance used either:~~
40 ~~(A) if a monograph exists, complies with the standards~~
41 ~~of the United States Pharmacopoeia or National~~
42 ~~Formulary monograph and the United States~~



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1 **human-drug-establishment under 21 U.S.C. 374, and the**
2 **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.~~

— See. 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

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Chapter 13.7. Medical Spas

Sec.  1. The definitions in IC 25-26-13-2 apply to this

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1 **chapter.**

2 **Sec. 2].** (a) As used in this chapter, "medical spa" means a
 3 facility or practice that:

4 (1) offers or provides medical health care services;
 5 (2) engages in the preparation, administration, or dispensing
 6 of prescription drugs or otherwise uses prescription drugs
 7 for intravenous, intramuscular, or subcutaneous delivery;
 8 and

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

12 (A) Weight loss.
 13 (B) Wellness.
 14 (C) Longevity.

15 (D) Cosmetic or aesthetic health ~~service~~services and
 16 treatments, including the preparation, administration,
 17 or dispensing of prescription drugs for:

18 (i) weight loss;
 19 (ii) botulinum toxin injections and dermal fillers;
 20 (iii) hair loss;
 21 (i~~ii~~v) hormone therapies; or
 22 (i~~iv~~v) parenteral nutrient therapies.

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

25 Sec. ~~2~~3]. (a) Beginning January 1, 2027, a medical spa is
 26 required to be registered under this chapter in order to do business
 27 in Indiana.

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

32 (1) The name of the medical spa.
 33 (2) The address of the medical spa.
 34 (3) The medical ~~spa's license number~~.

35 ~~(4) health care services intended to be provided at the~~
 36 ~~medical spa.~~

37 (4) The prescription drugs that are intended to be prepared,
 38 administered, dispensed, or otherwise used at the medical
 39 spa, including whether the prescription drug is compounded.

40 (5) The name and license number of the medical spa's
 41 licensed responsible ~~person~~practitioner as described in
 42 section ~~2~~5 of this chapter.



(c) The board may fine a person that operates an unregistered medical spa in an amount not to exceed five thousand dollars (\$5,000) and require that the person obtain registration under this chapter in order to do business in Indiana.

Sec. ~~4~~⁴. (a) The board shall establish and maintain a public data base that contains:

(1) the information specified in section ~~23~~[3](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. ~~44~~5. (a) A medical spa registered under this chapter must designate a responsible ~~person~~practitioner. The board may require a medical spa to receive the board's approval before a medical spa may designate a responsible ~~person~~practitioner to be in charge of more than one (1) location.

(b) A responsible ~~person~~ [practitioner who has prescriptive authority] 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. ~~66~~ 66. (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.

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

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

Sec. ~~47~~⁷. (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. ~~8~~⁸. (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~~ [pursuant] to the
~~public~~ [requirements set forth in IC 25-1-9-10].

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

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