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SENATE BILL No. 282

Proposed Changes to introduced printing by AM028206

DIGEST OF PROPOSED AMENDMENT

Medical spas. Moves the registration of a medical spa from the board of pharmacy to the medical licensing board of Indiana (board). Defines "practitioner". Modifies the information to be provided for registration of a medical spa. Specifies the maximum fine that the board may impose. Specifies requirements and responsibilities of the responsible practitioner. Includes treatments in the definition of "serious adverse event". Changes the language concerning when the board may suspend a medical spa registration. Prohibits a medical spa from providing health care services and cosmetic and lifestyle treatments in a location other than the medical spa, physician office, or other health care facility.

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]: **Sec. 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]: **Sec. 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]: **Sec. 41.3. "Bulk drug substance**
- 14 **manufacturing establishment", for purposes of IC 16-42-22.5, has**

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the meaning set forth in IC 16-42-22.5-3.

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

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 Bulk Drug Substances

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

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.

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

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. 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. (a) A person may not engage in compounding 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 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



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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



1 been inspected in the previous year and the previous three
2 (3) years, categorized by license type.

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

5 (A) conducts drug compounding; or

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

9 (i) A 503A pharmacy (as described in 21 U.S.C.
10 353a).

11 (ii) A 503B outsourcing facility (as described in 21
12 U.S.C. 353b).

13 (iii) A medical spa under
14 ~~IC 25-26-13~~ [\[IC 25-22.5-12\]](#). ~~<7>~~ [\[5\]](#).

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

18 (4) The nature and severity of any deficiency or violation
19 found by the regulating board in an investigation of a person
20 or facility specified in this subsection.

21 (5) The number of investigations conducted concerning drug
22 compounding.

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

25 (7) The number and type of disciplinary actions taken by
26 each board or state agency concerning the improper
27 marketing, advertising, or promotion of compounding drugs
28 or telehealth (as defined in IC 25-1-9.5-6) services.

29 (8) An assessment of the staffing and resources of each
30 regulating board concerning compounding drugs given the
31 high risk posed by the practice.

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

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

40 ~~<>~~ SECTION 6. ~~IC 25-26-13~~ [\[IC 25-22.5-12\]](#). ~~<7>~~ [\[5\]](#) IS ADDED
41 TO THE INDIANA CODE AS A NEW CHAPTER TO READ AS
42 FOLLOWS [EFFECTIVE JULY 1, 2026]:



Chapter 1 ~~3~~ [2]. ~~7~~ [5]. 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~~ [services and treatments], including the preparation, administration, or dispensing of prescription drugs for:

(i) weight loss;

(ii) botulinum toxin injections [and dermal fillers;

(iii) hair loss];

(i ~~ii~~ [v]) hormone therapies; or

(~~iv~~ [v]) parenteral nutrient therapies.

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

Sec. ~~2~~ [2. As used in this chapter, "practitioner" means any of the following:

(1) A physician licensed under IC 25-22.5.

(2) An advanced practice registered nurse who meets the requirements of IC 25-23-1-19.5.

(3) A physician assistant licensed under IC 25-27.5 who is delegated prescriptive authority under IC 25-27.5-5-6.

Sec. 3]. (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)~~ [health care services intended to be provided at the



1 medical spa.

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

5 (5) The name and license number of the medical spa's
 6 licensed responsible ~~person~~ practitioner described in
 7 section ~~4~~ 5 of this chapter.

8 [(6) The name and license number of the individuals and
 9 practitioners operating in the medical spa.

10 [(c) The board may fine a person that operates an unregistered
 11 medical spa in an amount not to exceed five thousand dollars
 12 (\$5,000) and require that the person obtain registration under this
 13 chapter in order to do business in Indiana.

14 Sec. ~~4~~ 5. (a) The board shall establish and maintain a
 15 public data base that contains:

16 (1) the information specified in section ~~4~~ 3(b) of this
 17 chapter for each registered medical spa; and

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

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

23 Sec. ~~4~~ 5. (a) A medical spa registered under this chapter
 24 must designate a responsible ~~person. The board may require a~~
 25 ~~medical spa to receive the board's approval before a medical spa~~
 26 ~~may designate a responsible person to be in charge of more than~~
 27 ~~one (1) location~~ practitioner who meets the following:

28 (1) Has prescriptive authority.

29 (2) Has education and training in the health care services
 30 and treatments being performed and medications being
 31 dispensed or administered in the medical spa].

32 (b) A responsible ~~person~~ practitioner shall be physically
 33 present at the medical spa location for a sufficient amount of time
 34 to comply with the responsibility of ensuring that the medical spa
 35 complies with the requirements of this chapter. [The board may
 36 require a medical spa to receive the board's approval before a
 37 medical spa may designate a responsible practitioner to be
 38 responsible for more than one (1) location.

39 (c) A responsible practitioner shall ensure that each individual
 40 working at the medical spa meets the following:

41 (1) Is licensed to perform the health care services and
 42 treatments the individual is to perform and that the health



care services and treatments are within the individual's scope of practice.

(2) Is properly trained in the performance of the health care services and treatments being provided by the individual.]

Sec. ~~<5>~~[6]. (a) As used in this section, "serious adverse event" means any negative medical occurrence associated with the use of a prescription medication [or treatment provided] 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 [treatment] 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>~~[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. ~~<7>~~[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>~~[pursuant to the requirements set forth in IC 25-1-9-10.

Sec. 9. A medical spa may not provide health care services and



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1 cosmetic and lifestyle treatments to a consumer at a location other
2 than] the medical spa ~~poses a danger to the public.~~
3 ~~—Sec. 8>~~ [office, a physician's office, or other licensed health
4 care facility.
5 Sec. 10]. The board may adopt rules under IC 4-22-2 that are
6 necessary to implement this chapter.[
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