Updated February 16, 2026 (8:38pm)

PRINTING CODE. Deletions appear in ~~<this style type>~~. Insertions appear in [this style type]. Typeface changes are shown in <> ~~this~~ <> <> ~~style~~ <> <> ~~type~~ <> or in []this[] []style[] []type[].

SENATE BILL No. 282

Proposed Changes to January 29, 2026 printing by AM028211

DIGEST OF PROPOSED AMENDMENT

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.

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

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

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

SECTION 2. 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 16-42-22.5-2.**

] SECTION ~~<1>~~[3]. 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: ~~<Pharmacy Compliance with the Federal Food, Drug, and Cosmetic Act~~

~~**Sec. 1. (a) Except as provided in subsection (b), this chapter applies to the following pharmacies that have a permit issued>**~~**[Restrictions on Bulk Drug Substances**

Sec. 1. (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. 2. 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 25-26-13:~~

~~(1) A pharmacy that is subject to Section 503A of the federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a).~~

~~(2) A pharmacy registered with>~~[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. 3. (a) A person may not engage in compounding unless the following requirements are met:

(1) Any bulk drug substance used has been reviewed as part of a new drug application and approved by] the federal Food and Drug Administration ~~<as an outsourcing facility that is subject to Section 503B of the federal Food, Drug, and Cosmetic Act (21 U.S.C. 353b).~~

~~(b) This chapter does not apply to>~~[under 21 U.S.C. 355.

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

(3) The bulk drug substance is accompanied by a valid certificate of analysis that contains all information that is material to the safety and effectiveness of the drug compounding using the bulk drug substance, including] the following:

[ ](~~<1) An entity licensed under IC 16-21.~~

~~(2) A pharmacy regulated by the board that holds a Category II permit as set forth in IC 25-26-13-17.~~

~~(3>~~[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 the amount present.

(D) Any additional information that the state department requires through the adoption of rules under IC 4-22-2.

(4) The bulk drug substance has had quality control testing conducted.

(5]) The compounding ~~<of a drug for animal use.~~

~~(4) The compounding of a drug for a specific individual due to an allergy or required dosage specification.~~

~~Sec. 2. (a) A pharmacy described in section 1(a)(1) of this chapter shall comply with Section 503A of the federal Food, Drug, and Cosmetic Act and any federal regulation promulgated under Section 503A of >~~[complies with]the federal Food, Drug, and Cosmetic Act.

(b) ~~<A pharmacy described in section 1(a)(2) of this chapter shall comply with Section 503B of the federal Food, Drug, and Cosmetic Act and any federal regulation promulgated under Section 503B of the federal Food, Drug, and Cosmetic Act.~~

~~Sec. 3. The>~~[Upon request by the Indiana board of pharmacy, a nonresident pharmacy (as defined in IC 25-26-17-2) that ships, mails, delivers, or dispenses a compounded drug into Indiana that is compounded using a bulk drug substance shall provide documentation demonstrating compliance with this chapter within a reasonable time, as determined by the] Indiana board of pharmacy ~~<may do>~~[based on the circumstances of the request.

(c) Any person engaging in the sale, transfer, or distribution of compounding drugs shall 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.

Sec. 4. (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:

(1) ~~<Investigate any alleged violation of this chapter.~~

~~(2) Enforce this chapter in accordance with IC 25-26-13-7.~~

~~(3) Request an injunction for a violation of this chapter in accordance with IC 25-26-13-28.~~

~~SECTION 2>~~[The number and type of professional licenses

issued, by license type, under which the license holder may engage in drug compounding.

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

(A) conduct drug compounding; or

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

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

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

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

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

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

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

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

SECTION 4]. IC 25-22.5-12.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2026]:

Chapter 12.5. 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 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;

(iv) hormone therapies; or

(v) parenteral nutrient therapies.

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

] (b) The term does not apply to ~~<a>~~[the following:

(1) A physician's office.

(2) A] facility or practice that is otherwise licensed by the state.

Sec. 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>~~[October] 1, 202~~<7>~~[6]. An application for registration for a medical spa must include the following:

[(1) The name of the medical spa, including the following:

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

] [ ](~~<1>~~[B]) The[legal] name of the medical spa.

(2) The address of the medical spa.

[(3) The website address of the medical spa.

] (~~<3>~~[4]) The medical health care services intended to be provided at the medical spa.[]

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

>[] (5) The name and license number of the medical spa's

licensed responsible practitioner described in section 5 of this chapter~~<.~~

~~(6) The name and license number of the individuals and practitioners operating in the medical spa.>~~[and the name of the responsible practitioner's collaborating physician, if applicable.

] (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. (a) The board shall establish and maintain a public data base that contains~~<.~~

~~(1)>~~ the information specified in section 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. 5. (a) A medical spa registered under this chapter must designate a responsible practitioner who meets the following:

(1) Has prescriptive authority.

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

(b) A responsible practitioner 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.~~< The board may require a medical spa to receive the board's approval before a medical spa may designate a>~~

[(c) A] responsible practitioner ~~<to be responsible for more than one (1) location.~~

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

(1) Is licensed to perform the health care services and 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>~~[Has received appropriate training] in the performance of the health care services and treatments being provided by the individual.~~<~~

~~Sec. 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. 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>~~[

Sec. 6]. (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 pursuant to the requirements set forth in IC 25-1-9-10.

Sec. ~~<9>~~[7]. A medical spa may not provide health care services and cosmetic and lifestyle treatments to a consumer at a location other than the medical spa office, a physician's office, or other licensed health care facility[unless the health care service or treatment is being performed in another location for educational

or training purposes of individuals who intend to provide these services or treatment.

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

Sec. 9. The board shall consult with the appropriate professional board that has oversight of a profession concerning any issues concerning the practice of the profession as it relates to providing services in a medical spa].

Sec. 10. The board may adopt rules under IC 4-22-2 that are necessary to implement this chapter.