PROPOSED AMENDMENT

SB 282 # 14

DIGEST

Compounding drugs; medical spas. Sets forth compounding requirements concerning bulk drug substances. Requires compliance with various federal laws. Makes changes to the registration of medical spas.

Page 1, delete lines 1 through 17, begin a new paragraph and insert:

"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 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: Restrictions on Bulk Drug Substances

Sec. 0.5. This chapter does not apply to the compounding of the drug for animal use.

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, 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. 3. (a) A person may not engage in compounding unless the following requirements are met:

(1) The bulk drug substance:

(A) is not research grade or veterinary grade; and

(B) complies with standards of the United States Pharmacopeia (USP) or National Formulary monograph and any applicable United States Pharmacopoeia chapter on pharmacy compounding.

(2) The bulk drug substance was manufactured by an establishment that is registered as a human drug establishment with the federal Food and Drug Administration under 21 U.S.C. 360.

(3) The bulk drug substance is accompanied by a valid certificate of analysis that includes the following:

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

(B) The country where the bulk drug substance was originally manufactured.

(C) 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 complies with the federal Food, Drug, and Cosmetic Act.

(b) 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 and IC 25-26-17-3 within a reasonable time, as determined by the Indiana board of pharmacy 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 drugs containing the bulk drug substance.

Sec. 4. (a) A pharmacy that is subject to Section 503A of the federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) shall comply with Section 503A of the federal Food, Drug, and Cosmetic Act, and any regulation promulgated under Section 503A of the federal Food, Drug, and Cosmetic Act.

(b) A pharmacy that is subject to Section 503B of the federal Food, Drug, and Cosmetic Act (21 U.S.C. 353b) shall comply with Section 503B of the federal Food, Drug, and Cosmetic Act, and any regulation promulgated under Section 503B of the federal Food, Drug, and Cosmetic Act.

(c) A manufacturer required to obtain approval under 21 U.S.C. 355 shall comply with federal new drug approval and current good manufacturing practice requirements.

Sec. 5. The Indiana board of pharmacy may investigate any alleged violation of this chapter.

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 and benefits posed by the practice of compounding.

(b) The report must include the following:

(1) 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 25-22.5-12.5);

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 related services.

(c) The report required by this section must be posted on the websites 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.".

Page 2, delete lines 1 through 17.

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

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

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

(1) A physician's office.

(2) A".

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

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

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

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

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

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

(4)".

Page 3, delete lines 19 through 21, begin a new line block indented and insert:

"**(5) The prescription drugs that are intended to be:**

(A) compounded (as defined in IC 16-42-22.5-2); and

(B) prepared, administered, dispensed, or otherwise used; at the medical spa.".

Page 3, line 22, delete "(5)" and insert "**(6)**".

Page 3, line 23, delete "." and insert "**and the name of the**

responsible practitioner's collaborating physician or supervising practitioner, if applicable.".

Page 3, delete lines 24 through 25.

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

Page 3, delete lines 32 through 35.

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

Page 4, delete lines 7 through 9.

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

Page 4, delete lines 28 through 30.

Page 4, line 32, delete "five (5)" and insert "**fifteen (15)**".

Page 4, delete lines 41 through 42.

Page 5, delete lines 1 through 11, begin a new paragraph and insert:

"**Sec. 7. The board may investigate a responsible practitioner concerning any claim of a violation of this chapter and forward any substantiated claim to the governing board of the responsible practitioner.**

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

Page 5, line 14, delete "office, a physician's office, or other licensed" and insert "**office 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. 10. (a) A medical spa shall comply with the advertising requirements set forth in IC 25-1-10.3.

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

Sec. 11. (a) 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.

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

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

"SECTION 5. IC 25-26-13-4, AS AMENDED BY P.L.93-2024, SECTION 186, IS AMENDED TO READ AS FOLLOWS

[EFFECTIVE JULY 1, 2026]: Sec. 4. (a) The board may:

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

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

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

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

(5) impound, embargo, confiscate, or otherwise prevent from disposition any drugs, medicines, chemicals, poisons, or devices which by inspection are deemed unfit for use or would be dangerous to the health and welfare of the citizens of the state of Indiana; the board shall follow those embargo procedures found in IC 16-42-1-18 through IC 16-42-1-31, and persons may not refuse to permit or otherwise prevent members of the board or their representatives from entering such places and making such inspections;

(6) prescribe minimum standards with respect to physical characteristics of pharmacies, as may be necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public;

(7) subject to IC 25-1-7, investigate complaints, subpoena witnesses, schedule and conduct hearings on behalf of the public interest on any matter under the jurisdiction of the board;

(8) prescribe the time, place, method, manner, scope, and subjects of licensing examinations which shall be given at least twice annually; ~~and~~

(9) perform such other duties and functions and exercise such other powers as may be necessary to implement and enforce this chapter; **and**

(10) investigate any alleged violation of IC 16-42-22.5.

(b) The board shall adopt rules under IC 4-22-2 for the following:

(1) Establishing standards for the competent practice of pharmacy.

(2) Establishing the standards for a pharmacist to counsel individuals regarding the proper use of drugs.

(3) Establishing standards and procedures before January 1, 2006,

to ensure that a pharmacist:

(A) has entered into a contract that accepts the return of expired drugs with; or

(B) is subject to a policy that accepts the return of expired drugs of;

a wholesaler, manufacturer, or agent of a wholesaler or manufacturer concerning the return by the pharmacist to the wholesaler, the manufacturer, or the agent of expired legend drugs or controlled drugs. In determining the standards and procedures, the board may not interfere with negotiated terms related to cost, expenses, or reimbursement charges contained in contracts between parties, but may consider what is a reasonable quantity of a drug to be purchased by a pharmacy. The standards and procedures do not apply to vaccines that prevent influenza, medicine used for the treatment of malignant hyperthermia, and other drugs determined by the board to not be subject to a return policy. An agent of a wholesaler or manufacturer must be appointed in writing and have policies, personnel, and facilities to handle properly returns of expired legend drugs and controlled substances.

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

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

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

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

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

(2) Security of the electronic transmission.

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

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

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

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

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

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

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

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

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

(2) A thermochromic mark on the front and the back of the prescription that:

(A) is at least one-fourth (1/4) of one (1) inch in height and width; and

(B) changes from blue to clear when exposed to heat.

(g) The board may contract with a supplier to implement and manage the prescription drug program described in subsection (e). The supplier must:

(1) have been audited by a third party auditor using the SAS 70 audit or an equivalent audit for at least the three (3) previous years; and

(2) be audited by a third party auditor using the SAS 70 audit or an equivalent audit throughout the duration of the contract;

in order to be considered to implement and manage the program.

(h) The board shall adopt rules under IC 4-22-2 concerning:

(1) professional determinations made under IC 35-48-4-14.7(d); and

(2) the determination of a relationship on record with the pharmacy under IC 35-48-4-14.7.

(i) The board may:

(1) review professional determinations made by a pharmacist; and

(2) take appropriate disciplinary action against a pharmacist who violates a rule adopted under subsection (h) concerning a professional determination made;

under IC 35-48-4-14.7 concerning the sale of ephedrine and pseudoephedrine.".

Renumber all SECTIONS consecutively.

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