January 30, 2018

SENATE BILL No. 339

DIGEST OF SB 339 (Updated January 29, 2018 4:19 pm - DI 84)

Citations Affected: IC 25-26; IC 34-30.

Synopsis: Controlled substance dispensing. Provides that a pharmacy or pharmacist may not sell or dispense a controlled drug in schedule II unless the pharmacy or pharmacist offers to sell or dispense the drug to the patient or patient's representative in a lockable vial. Provides for immunity from liability for a pharmacy, pharmacy personnel, and pharmacist in certain circumstances.

Effective: July 1, 2018.

Merritt, Head, Alting

January 4, 2018, read first time and referred to Committee on Civil Law.
January 29, 2018, amended, reported favorably — Do Pass.

January 30, 2018

Second Regular Session 120th General Assembly (2018)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2017 Regular Session of the General Assembly.

SENATE BILL No. 339

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

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

SECTION 1. IC 25-26-13-2, AS AMENDED BY P.L.89-2015, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: Sec. 2. As used in this chapter:

"Administering" means the direct application of a drug to the body of a person by injection, inhalation, ingestion, or any other means.

"Board" means the Indiana board of pharmacy.

"Controlled drugs" are those drugs on schedules I through V of the federal Controlled Substances Act or on schedules I through V of IC 35-48-2.

"Counseling" means effective communication between a pharmacist and a patient concerning the contents, drug to drug interactions, route, dosage, form, directions for use, precautions, and effective use of a drug or device to improve the therapeutic outcome of the patient through the effective use of the drug or device.

"Dispensing" means issuing one (1) or more doses of a drug in a suitable container with appropriate labeling for subsequent administration to or use by a patient.

"Drug" means:

(1) articles or substances recognized in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them;

(2) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

(3) articles other than food intended to affect the structure or any function of the body of man or animals; or

(4) articles intended for use as a component of any article specified in subdivisions (1) through (3) and devices.

"Drug order" means a written order in a hospital or other health care institution for an ultimate user for any drug or device, issued and signed by a practitioner, or an order transmitted by other means of communication from a practitioner, which is immediately reduced to writing by the pharmacist, registered nurse, or other licensed health care practitioner authorized by the hospital or institution. The order shall contain the name and bed number of the patient; the name and strength or size of the drug or device; unless specified by individual institution policy or guideline, the amount to be dispensed either in quantity or days; adequate directions for the proper use of the drug or device when it is administered to the patient; and the name of the prescriber.

"Drug regimen review" means the retrospective, concurrent, and prospective review by a pharmacist of a patient's drug related history that includes the following areas:

(1) Evaluation of prescriptions or drug orders and patient records for drug allergies, rational therapy contradictions, appropriate dose and route of administration, appropriate directions for use, or duplicative therapies.

(2) Evaluation of prescriptions or drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions.

(3) Evaluation of prescriptions or drug orders and patient records for adverse drug reactions.

(4) Evaluation of prescriptions or drug orders and patient records for proper utilization and optimal therapeutic outcomes.

"Drug utilization review" means a program designed to measure and assess on a retrospective and prospective basis the proper use of drugs.

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component part or accessory, which is:

(1) recognized in the official United States Pharmacopoeia, official National Formulary, or any supplement to them;

(2) intended for use in the diagnosis of disease or other conditions or the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(3) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

"Electronic data intermediary" means an entity that provides the infrastructure that connects a computer system or another electronic device used by a prescribing practitioner with a computer system or another electronic device used by a pharmacy to facilitate the secure transmission of:

(1) an electronic prescription order;

(2) a refill authorization request;

(3) a communication; and

(4) other patient care information;

between a practitioner and a pharmacy.

"Electronic signature" means an electronic sound, symbol, or process:

(1) attached to or logically associated with a record; and

(2) executed or adopted by a person;

with the intent to sign the record.

"Electronically transmitted" or "electronic transmission" means the transmission of a prescription in electronic form. The term does not include the transmission of a prescription by facsimile.

"Investigational or new drug" means any drug which is limited by state or federal law to use under professional supervision of a practitioner authorized by law to prescribe or administer such drug.

"Legend drug" has the meaning set forth in IC 16-18-2-199.

"License" and "permit" are interchangeable and mean a written certificate from the Indiana board of pharmacy for the practice of pharmacy or the operation of a pharmacy.

"Lockable vial" means a disposable vial that:

(1) has special packaging as defined in 15 U.S.C. 1471; and

(2) has a locking-cap closure mechanism that can only be unlocked electronically or physically using a:

(A) numeric or alphanumeric combination code that is selected by the patient; or

(B) biometric.

"Medication therapy management" means a distinct service or group of services that optimize therapeutic outcomes for individuals that are independent of, but may occur in conjunction with, the provision of a medication or medical device. The term includes the following services:

(1) Performing or obtaining assessments of an individual's health status.

(2) Formulating a medication treatment plan.

(3) Selecting, initiating, modifying, or administering medication therapy.

(4) Monitoring and evaluating an individual's response to therapy, including safety and effectiveness.

(5) Performing a comprehensive medication review to identify, resolve, and prevent medication related problems, including adverse drug events.

(6) Documenting the care delivered and communicating essential information to the patient's other health care providers.

(7) Providing education and training designed to enhance patient understanding and appropriate use of the individual's medications.

(8) Providing information and support services and resources designed to enhance patient adherence with the individual's therapeutic regimens, including medication synchronization.

(9) Coordinating and integrating medication therapy management services within the broader health care services being provided to an individual.

(10) Providing other patient care services allowable by law.

"Nonprescription drug" means a drug that may be sold without a prescription and that is labeled for use by a patient in accordance with state and federal laws.

"Person" means any individual, partnership, copartnership, firm, company, corporation, association, joint stock company, trust, estate, or municipality, or a legal representative or agent, unless this chapter expressly provides otherwise.

"Practitioner" has the meaning set forth in IC 16-42-19-5.

"Pharmacist" means a person licensed under this chapter.

"Pharmacist intern" means a person who is:

(1) permitted by the board to engage in the practice of pharmacy while under the personal supervision of a pharmacist and who is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

(2) a graduate of an approved college of pharmacy or a graduate

who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate and who is permitted by the board to obtain practical experience as a requirement for licensure as a pharmacist;

(3) a qualified applicant awaiting examination for licensure; or

(4) an individual participating in a residency or fellowship program.

"Pharmacy" means any facility, department, or other place where prescriptions are filled or compounded and are sold, dispensed, offered, or displayed for sale and which has as its principal purpose the dispensing of drug and health supplies intended for the general health, welfare, and safety of the public, without placing any other activity on a more important level than the practice of pharmacy.

"The practice of pharmacy" or "the practice of the profession of pharmacy" means a patient oriented health care profession in which pharmacists interact with and counsel patients and with other health care professionals concerning drugs and devices used to enhance patients' wellness, prevent illness, and optimize the outcome of a drug or device, by accepting responsibility for performing or supervising a pharmacist intern or an unlicensed person under section 18.5 of this chapter to do the following acts, services, and operations:

(1) The offering of or performing of those acts, service operations, or transactions incidental to the interpretation, evaluation, and implementation of prescriptions or drug orders.

(2) The compounding, labeling, administering, dispensing, or selling of drugs and devices, including radioactive substances, whether dispensed under a practitioner's prescription or drug order or sold or given directly to the ultimate consumer.

(3) The proper and safe storage and distribution of drugs and devices.

(4) The maintenance of proper records of the receipt, storage, sale, and dispensing of drugs and devices.

(5) Counseling, advising, and educating patients, patients' caregivers, and health care providers and professionals, as necessary, as to the contents, therapeutic values, uses, significant problems, risks, and appropriate manner of use of drugs and devices.

(6) Assessing, recording, and reporting events related to the use of drugs or devices.

(7) Provision of the professional acts, professional decisions, and professional services necessary to maintain all areas of a patient's pharmacy related care as specifically authorized to a pharmacist

under this article.

(8) Provision of medication therapy management.

"Prescription" means a written order or an order transmitted by other means of communication from a practitioner to or for an ultimate user for any drug or device containing:

(1) the name and address of the patient;

(2) the date of issue;

(3) the name and strength or size (if applicable) of the drug or device;

(4) the amount to be dispensed (unless indicated by directions and duration of therapy);

(5) adequate directions for the proper use of the drug or device by the patient;

(6) the name of the practitioner; and

(7) if the prescription:

(A) is in written form, the signature of the practitioner; or

(B) is in electronic form, the electronic signature of the practitioner.

"Qualifying pharmacist" means the pharmacist who will qualify the pharmacy by being responsible to the board for the legal operations of the pharmacy under the permit.

"Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication charts or files, computerized records, or other written indicia, documents, or objects which are used in any way in connection with the purchase, sale, or handling of any drug or device.

"Sale" means every sale and includes:

(1) manufacturing, processing, transporting, handling, packaging, or any other production, preparation, or repackaging;

(2) exposure, offer, or any other proffer;

(3) holding, storing, or any other possession;

(4) dispensing, giving, delivering, or any other supplying; and

(5) applying, administering, or any other using.

SECTION 2. IC 25-26-13-34 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: **Sec. 34. (a) This section:**

(1) applies to a pharmacy and a pharmacist authorized under this article to sell or dispense a controlled drug; and

(2) does not apply to a pharmacy or pharmacist who sells or dispenses a controlled drug for use by a patient whose physical condition prevents the patient from opening a lockable vial, as determined by the patient's treating

physician.

(b) A pharmacy or pharmacist:

(1) shall not sell or dispense a drug:

(A) that is classified as a controlled drug in schedule II under federal law;

(B) to a patient or a patient's representative; and

(C) for the patient's use in a setting other than an inpatient setting;

unless the pharmacist offers to dispense the drug to the patient or patient's representative in a lockable vial;

(2) shall bill the manufacturer of a drug that is sold or dispensed in a lockable vial under subdivision (1) for the cost of the lockable vial; and

(3) shall not bill the patient for the cost of the lockable vial.

(c) A pharmacy, an employee of a pharmacy, and a pharmacist:

(1) may disclose:

(A) in person to the individual described in subsection (b)(1)(B);

(B) online in a password protected patient account; or

(C) verbally by telephone after the patient or patient's representative verbally confirms the following information possessed by the pharmacy:

(i) The patient's date of birth.

(ii) Either the patient's driver's license or government issued identification card number or the patient's Social Security number;

the combination code or biometric of a locking-cap closure mechanism on a lockable vial; and

(2) is immune from civil liability arising from a good faith disclosure described in subdivision (1).

SECTION 3. IC 25-26-17-6 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: Sec. 6. A nonresident pharmacy registered under this chapter must comply with the **following:**

(1) The laws and rules of the state in which it is domiciled.

(2) The controlled drug dispensing requirement of IC 25-26-13-34.

SECTION 4. IC 25-26-18-2 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: Sec. 2. A mail order or Internet based pharmacy shall comply with the following:

(1) The licensure laws of the state in which the mail order or Internet based pharmacy is domiciled.

(2) The drug substitution laws of Indiana.

(3) The controlled drug dispensing requirement of IC 25-16-13-34.

SECTION 5. IC 34-30-2-101.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: **Sec. 101.2. IC 25-26-13-34 (Concerning pharmacy or pharmacist disclosure of a combination code or biometric on a lockable vial for a controlled drug).**

COMMITTEE REPORT

Madam President: The Senate Committee on Civil Law, to which was referred Senate Bill No. 339, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 7, line 9, delete "drug is sold or dispensed" and insert "**pharmacist offers to dispense the drug to the patient or patient's representative**".

and when so amended that said bill do pass.

(Reference is to SB 339 as introduced.)

HEAD, Chairperson

Committee Vote: Yeas 5, Nays 1.