HOUSE BILL No. 1246

DIGEST OF INTRODUCED BILL

Citations Affected: IC 25-26; IC 35-48-7-2.6.

Synopsis: Pharmacy matters. Allows a pharmacy that holds a retail permit to offer drugs and devices to a long term care facility and a health facility. Allows a pharmacy to transfer, upon the request of a patient, certain prescriptions for the patient that the pharmacy has received but not filled to another pharmacy. Provides that injectable epinephrine or glucagon must have an expiration date of not less than 12 months from the date that the pharmacy dispenses the injectable epinephrine or glucagon to a person. Provides that an automated dispensing system that meets certain requirements may be operated in a location other than through a registered remote dispensing facility. Allows a qualifying pharmacist who is absent to have a designee in the pharmacist's place at a remote dispensing facility. Allows the board of pharmacy to establish continuing education rules for pharmacy technicians who are at a remote dispensing facility that is not staffed by a pharmacist. Provides that auditory communication must be available, as needed, with the remote dispensing facility and the qualifying pharmacist. Requires the board to adopt emergency rules concerning automated dispensing systems. Provides that the term "wholesale distribution", for purposes of the wholesale legend drug distributor laws, does not include the sale or transfer of a drug by a charitable organization to: (1) a nonprofit affiliate of the organization; or (2) a nonprofit entity that is not affiliated with the organization; to the extent permitted by law. Adds gabapentin to the definition of "controlled substance" for purposes of the Indiana scheduled prescription electronic collection and tracking (INSPECT) program.

Effective: June 1, 2019; July 1, 2019.

Davisson

January 10, 2019, read first time and referred to Committee on Public Health.

Introduced

First Regular Session of the 121st General Assembly (2019)

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 2018 Regular and Special Session of the General Assembly.

HOUSE BILL No. 1246

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 25-26-13-17, AS AMENDED BY P.L.202-2017, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 17. (a) The board shall establish classes of pharmacy permits as follows:

Category I. A retail permit for a pharmacy that provides pharmaceutical care to the general public by the dispensing of a drug or device.

Category II. An institutional permit for hospitals, clinics, health care facilities, sanitariums, nursing homes, or dispensaries that offer pharmaceutical care by dispensing a drug product to an inpatient under a drug order or to an outpatient of the institution under a prescription.

Category III. A permit for a pharmacy that provides closed door, central fill, mail order, or other processing operations that are not open to the general public but include:

(A) traditional pharmacy functions; or

(B) nontraditional pharmacy functions, such as infusion,

nuclear pharmacy, or sterile compounding.

(b) Except for when registration as a remote dispensing facility (as defined in IC 25-26-13.5-3) is required under IC 25-26-13.5, the board may approve a remote or mobile location for Category I, II, or III permits. Pharmacy practice in a mobile or remote location may include, but is not limited to, telepharmacy, automated dispensing, or delivery of cognitive services.

(c) A hospital or hospital system holding a Category II permit may offer drugs or devices:

(1) to:

(A) an employee, student, or volunteer of the hospital or hospital system;

(B) a retiree who is participating in a retirement, pension, or benefit program administered by the hospital or hospital system;

(C) an independent contractor who has an exclusive relationship with the hospital or hospital system;

(D) a member of the hospital's or hospital system's governing board; or

(E) a member of the hospital's or hospital system's medical staff; and

(2) to dependents of the individuals listed in subdivision (1);

for their own use.

(d) Hospitals holding a Category II permit may operate remote locations within a reasonable distance of the licensed area, as determined by the board, after:

(1) filing an application on a form prepared by the board;

(2) having each location inspected by the board; and

(3) obtaining approval from the board.

(e) Any applicable rule governing the practice of pharmacy in Indiana shall apply to all permits under this section.

(f) After June 30, 2012, a person with:

(1) a Type I permit shall be treated as holding a Category I permit;

(2) a Type II permit shall be treated as holding a Category II permit; and

(3) a Type III, IV, V, or VI permit shall be treated as holding a Category III permit.

The change in the name of the permit does not change the expiration date of the permit.

(g) After June 30, 2012, a reference in any rule or other document to:

(1) a Type I permit shall be treated as a reference to a Category I

permit;

(2) a Type II permit shall be treated as a reference to a Category II permit; or

(3) a Type III, IV, V, or VI permit shall be treated as a reference to a Category III permit.

(h) A pharmacy holding a Category I permit may offer drugs or devices to the following:

(1) A long term care facility licensed under or subject to IC 16-28-2.

(2) A health facility licensed under IC 16-28.

(3) An assisted living facility registered with the office of the secretary of family and social services.

SECTION 2. IC 25-26-13-24.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: **Sec. 24.8. Upon request of a patient, a pharmacy may transfer to another pharmacy a prescription for the patient that the pharmacy has received but not filled unless:**

(1) prohibited in writing on the prescription by the prescriber; or

(2) otherwise prohibited by federal law.

SECTION 3. IC 25-26-13-25.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: **Sec. 25.3. A pharmacy may not dispense injectable epinephrine or glucagon to a person unless the injectable epinephrine or glucagon has an expiration date of not less than twelve (12) months from the date that the drug is dispensed.**

SECTION 4. IC 25-26-13.5-1.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: **Sec. 1.5. (a) As used in this chapter, "automated dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for the drugs.**

(b) The term does not include an automated dispensing system that is located in a hospital licensed under IC 16-21-2, an ambulatory outpatient surgical center licensed under IC 16-21-2, a health facility licensed under IC 16-28, or a pharmacy licensed under IC 25-26-13.

SECTION 5. IC 25-26-13.5-3, AS ADDED BY P.L.202-2017,

SECTION 12, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 3. As used in this chapter, "remote dispensing facility" means a facility ~~or an automated dispensing system~~ where prescription drugs are prepared or dispensed without the requirement of the use of an onsite pharmacist and where pharmacist supervision may be provided remotely. However, the term does not include a facility ~~or an automated dispensing system~~ that is located in a hospital licensed under IC 16-21-2, an ambulatory outpatient surgical center licensed under IC 16-21-2, ~~or~~ a health facility licensed under IC 16-28, **or an automated dispensing system.**

SECTION 6. IC 25-26-13.5-6.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: **Sec. 6.5. (a) The registration required under this chapter is in addition to any other registration or permit required under this article.**

(b) The board shall establish a registration procedure for automated dispensing systems. An application for registration of an automated dispensing system must include the following information:

(1) A description of the automated dispensing system being used at the facility, including information concerning any of the following:

(A) Telepharmacy communication.

(B) Electronic record keeping.

(C) Electronic verification systems.

(2) Operating specifications of the automated dispensing system, including the following:

(A) Location of the facility using the automated dispensing system.

(B) Ownership of the automated dispensing system.

(C) Identification of personnel responsible for operation of the automated dispensing system.

(3) A scale drawing that illustrates the layout and location of the automated dispensing system.

(4) Identification of the proposed supervising pharmacy.

(c) A supervising pharmacy of an automated dispensing system must be located in Indiana and licensed under this article.

SECTION 7. IC 25-26-13.5-6.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: **Sec. 6.7. (a) Before a pharmacy may operate an automated dispensing system, the automated dispensing system must be registered with the board under this chapter and**

in the manner prescribed by the board.

(b) The board shall establish minimum standards and practices that ensure the safety, accuracy, security, record keeping, and patient confidentiality of an automated dispensing system.

SECTION 8. IC 25-26-13.5-8, AS ADDED BY P.L.202-2017, SECTION 12, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 8. (a) The qualifying pharmacist and a pharmacist on duty are responsible for ensuring that the supervising pharmacy and remote dispensing facility are sufficiently staffed to avoid the risk of harm to public health and safety.

(b) In order to serve as a qualifying pharmacist, the pharmacist must be in good standing with the board.

(c) A qualifying pharmacist may have this designation for only one (1) supervising pharmacy and for one (1) remote dispensing facility at a time.

(d) A qualifying pharmacist must be able to be physically at the remote dispensing facility within a certain time set by the board to address emergencies and safety issues that arise. **However, in the qualifying pharmacist's absence the qualifying pharmacist may designate another pharmacist to fulfill the qualifying pharmacist's duties at the remote dispensing facility.**

(e) A qualifying pharmacist shall visit a remote dispensing facility at least as often as required by the board to inspect the facility and address personnel matters. The qualifying pharmacist shall complete any forms required by the board concerning the required inspection and maintain the records in a manner specified by the board.

(f) If the remote dispensing facility is located at a hospital or physician clinic and uses an automated dispensing machine, the qualifying pharmacist shall maintain an up to date inventory of any schedule II controlled substances. The qualifying pharmacist shall at least monthly inventory all controlled substances.

(g) The qualifying pharmacist shall develop and implement a continuous quality improvement program. The program must include a reporting mechanism for errors that occur concerning the remote dispensing facility. Information concerning the program must be available to the board upon request.

SECTION 9. IC 25-26-13.5-9, AS ADDED BY P.L.202-2017, SECTION 12, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 9. (a) There must be at least one (1) pharmacist working at a remote dispensing facility for every six (6) pharmacist interns, licensed pharmacy technicians, and pharmacy technicians in training at the supervising pharmacy and remote dispensing facility.

However, an individual whose only duty is to act as the cashier is not included in the number of employees that may work for one (1) pharmacist under this subsection.

(b) A remote dispensing facility that is not staffed by a pharmacist must be staffed by at least one (1) pharmacy technician who meets the following requirements:

(1) Is licensed under IC 25-26-19.

(2) Has at least two thousand (2,000) hours of experience working as a pharmacy technician in a pharmacy licensed under this article and under the direct supervision of a pharmacist.

(3) Has successfully passed a certification examination offered by the Pharmacy Technician Certification Board or another nationally recognized certification body approved by the board.

(4) If the remote dispensing facility is located in a hospital or physician clinic setting, either:

(A) has graduated from a pharmacy technician training program accredited by the American Council of Pharmaceutical Education or the American Society of Health System Pharmacists; or

(B) obtained the hours described in subdivision (2) before July 1, 2017.

(5) Is supervised by a pharmacist at the supervising pharmacy at all times that the remote dispensing facility is operational. As used in this subdivision, supervision does not require that the pharmacist be physically present at the remote dispensing facility as long as the pharmacist is supervising telepharmacy operations electronically through a computer link, video link, and audio link.

(6) Is currently in good standing with the board.

(c) A pharmacy technician in training may not work at a remote dispensing facility unless a pharmacist is on site.

(d) The board shall adopt rules that require pharmacy technicians working at a remote dispensing facility that is not staffed by a pharmacist to complete continuing education requirements established by the board.

SECTION 10. IC 25-26-13.5-11, AS ADDED BY P.L.202-2017, SECTION 12, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 11. (a) A supervising pharmacy of a remote dispensing facility must maintain a video and audio communication system that provides for effective communication between the supervising pharmacy, the remote dispensing facility, and any consumers. The system must do the following:

(1) Provide an adequate number of views of the entire remote

dispensing facility.

(2) Facilitate adequate pharmacist supervision.

(3) Allow an appropriate exchange of visual, verbal, and written communications for patient counseling and other matters concerning the lawful transaction of business.

(b) The remote dispensing facility must retain a recording of facility surveillance, excluding patient communications, for at least forty-five (45) days.

(c) A qualifying pharmacist is adequately supervising through the use of video surveillance by maintaining constant visual supervision and auditory communication with the remote dispensing facility and by maintaining full supervisory control of the automated system, if applicable. **The auditory communication must be available, as needed, with the remote dispensing facility and the qualifying pharmacist.**

(d) A video monitor that is being used to properly identify and communicate with consumers must meet the following requirements:

(1) Be at least twelve (12) inches wide.

(2) Be high definition.

(3) Provide both the supervising pharmacy and the remote dispensing facility with direct visual contact between the pharmacist and the consumer.

(4) Be secure and compliant with the federal Health Insurance Portability and Accountability Act (HIPAA).

(e) If any component of the communication system is not in operating order, the remote dispensing facility shall remain closed until the communication system is fully operational, unless a pharmacist is located at the remote dispensing facility.

SECTION 11. IC 25-26-13.5-18, AS AMENDED BY P.L.209-2018, SECTION 11, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JUNE 1, 2019]: Sec. 18. (a) The board may adopt rules under IC 4-22-2 necessary to implement this chapter.

(b) The Indiana board of pharmacy shall ~~not later than July 1, 2018,~~ adopt rules under IC 4-22-2, including emergency rules in the manner provided under IC 4-22-2-37.1, to implement **sections 6.5 and 6.7 of** this chapter with respect to telepharmacy. This subsection expires July 1, ~~2019.~~ **2020.**

SECTION 12. IC 25-26-14-11, AS AMENDED BY P.L.212-2005, SECTION 45, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 11. As used in this chapter, "wholesale distribution" means to distribute legend drugs to persons other than a consumer or patient. The term does not include:

(1) a sale or transfer between a division, a subsidiary, a parent, an affiliated, or a related company under the common ownership and control of a corporate entity;

(2) the purchase or acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for the hospital's or health care entity's own use from the group purchasing organization or from other hospitals or health care entities that are members of the organization;

(3) the sale **or transfer** of a drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code, to:

(A) a nonprofit affiliate of the organization; **or**

(B) a nonprofit entity described in Section 501(c)(3) of the Internal Revenue Code that is not affiliated with the organization;

to the extent otherwise permitted by law;

(4) the sale of a drug among hospitals or other health care entities that are under common control;

(5) the sale of a drug for emergency medical reasons, including transfers of legend drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, if the gross dollar value of the transfers does not exceed five percent (5%) of the total legend drug sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period;

(6) the sale of a drug or the dispensing of a drug pursuant to a prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives;

(8) the sale of blood and blood components intended for transfusion;

(9) the sale of a drug by a retail pharmacy to a practitioner (as defined in IC 25-26-13-2) for office use, if the gross dollar value of the transfers does not exceed five percent (5%) of the retail pharmacy's total legend drug sales during any twelve (12) consecutive months;

(10) the sale of a drug by a retail pharmacy that is ending its business and liquidating its inventory to another retail pharmacy;

(11) drug returns by a hospital, health care entity, or charitable institution conducted under 21 CFR 203.23;

(12) the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use;

(13) the distribution of prescription drugs by the original

manufacturer of the finished form of the prescription drug or the distribution of the co-licensed products by a partner of the original manufacturer of the finished form of the prescription drug; or

(14) drug returns that meet criteria established by rules adopted by the board.

SECTION 13. IC 35-48-7-2.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: **Sec. 2.6. As used in this chapter, "controlled substance" has the meaning set forth in IC 35-48-1-9. The term includes gabapentin.**

SECTION 14. **An emergency is declared for this act.**