SENATE BILL No. 107

DIGEST OF INTRODUCED BILL

Citations Affected: IC 35-31.5-2-172; IC 35-48.

Synopsis: INSPECT registration for dispensers of controlled substances. Requires certain registered dispensers of controlled substances to be registered with the INSPECT program.

Effective: July 1, 2018.

Merritt

January 3, 2018, read first time and referred to Committee on Health and Provider Services.

Introduced

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. 107

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 35-31.5-2-172, AS ADDED BY P.L.114-2012, SECTION 67, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: Sec. 172. "INSPECT" **or "INSPECT program",** for purposes of **IC 35-48-3-3 and** IC 35-48-7, has the meaning set forth in IC 35-48-7-5.2.

SECTION 2. IC 35-48-3-3, AS AMENDED BY P.L.185-2013, SECTION 6, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: Sec. 3. (a) Every person who manufactures or distributes any controlled substance within this state or who proposes to engage in the manufacture or distribution of any controlled substance within this state, must obtain biennially a registration issued by the board in accordance with the board's rules.

(b) Every person who dispenses or proposes to dispense any controlled substance within Indiana must have a registration issued by the board in accordance with the board's rules. A registration issued to a dispenser under this subsection expires whenever the dispenser's license as a practitioner expires. The board shall renew a dispenser's

registration under this subsection concurrently with any state license authorizing the dispenser to act as a practitioner.

(c) This subsection is effective January 1, 2014. An owner must have a registration issued by the board in accordance with the board's rules. An owner shall adopt reasonable procedures to ensure that employed or contracted individuals who are dispensing controlled substances in the office, facility, clinic, or location owned or controlled by the owner dispense the controlled substances in a manner that complies with laws, rules, and regulations.

(d) Persons registered by the board under this article to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this chapter.

(e) The following persons need not register and may lawfully possess controlled substances under this article:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if the agent or employee is acting in the usual course of the agent's or employee's business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment.

(3) An ultimate user or a person in possession of any controlled substance under a lawful order of a practitioner or in lawful possession of a schedule V substance.

(f) The board may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers if it finds it consistent with the public health and safety.

(g) A separate registration is required at each principal place of business or professional practice where the applicant:

(1) manufactures, distributes, dispenses, or possesses controlled substances; and

(2) employs or contracts with individuals to dispense controlled substances. This subdivision is effective January 1, 2014.

(h) The board may inspect the establishment of a registrant or applicant for registration in accordance with the board's rules.

(i) Beginning January 1, 2014, the attorney general may file a petition in circuit or superior court to obtain an injunction against a violation of this chapter by an owner. In an action filed by the attorney general under this subsection, the court may:

(1) issue an injunction;

(2) order the owner to pay a civil penalty not to exceed five thousand dollars ($5,000);

(3) order the owner to pay the state the reasonable costs of the attorney general's investigation and prosecution related to the action; and

(4) provide the appointment of a receiver.

(j) Beginning July 1, 2018, a person who applies for or renews a registration under subsection (b) must also register or be registered with the INSPECT program in the manner prescribed by the board.

SECTION 3. IC 35-48-7-8.1, AS AMENDED BY P.L.164-2017, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: Sec. 8.1. (a) The board shall provide for an ephedrine, pseudoephedrine, and controlled substance prescription monitoring program that includes the following components:

(1) Each time ephedrine, pseudoephedrine, or a controlled substance designated by the board under IC 35-48-2-5 through IC 35-48-2-10 is dispensed, the dispenser shall transmit to the INSPECT program the following information:

(A) The ephedrine, pseudoephedrine, or controlled substance recipient's name.

(B) The ephedrine, pseudoephedrine, or controlled substance recipient's or the recipient representative's identification number or the identification number or phrase designated by the INSPECT program.

(C) The ephedrine, pseudoephedrine, or controlled substance recipient's date of birth.

(D) The national drug code number of the ephedrine, pseudoephedrine, or controlled substance dispensed.

(E) The date the ephedrine, pseudoephedrine, or controlled substance is dispensed.

(F) The quantity of the ephedrine, pseudoephedrine, or controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) The dispenser's United States Drug Enforcement Agency registration number.

(I) The prescriber's United States Drug Enforcement Agency registration number.

(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

(K) Other data required by the board.

(2) The information required to be transmitted under this section

must be transmitted as follows:

(A) Before July 1, 2015, not more than seven (7) days after the date on which ephedrine, pseudoephedrine, or a controlled substance is dispensed.

(B) Beginning July 1, 2015, and until December 31, 2015, not more than three (3) days after the date on which ephedrine, pseudoephedrine, or a controlled substance is dispensed.

(C) Beginning January 1, 2016, and thereafter, not more than twenty-four (24) hours after the date on which ephedrine, pseudoephedrine, or a controlled substance is dispensed. However, if the dispenser's pharmacy is closed the day following the dispensing, the information must be transmitted by the end of the next business day.

(3) A dispenser shall transmit the information required under this section by:

(A) uploading to the INSPECT web site;

(B) a computer diskette; or

(C) a CD-ROM disk;

that meets specifications prescribed by the board.

(4) The board may require that prescriptions for ephedrine, pseudoephedrine, or controlled substances be written on a one (1) part form that cannot be duplicated. However, the board may not apply such a requirement to prescriptions filled at a pharmacy with a Category II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The board may not require multiple copy prescription forms for any prescriptions written. The board may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be approved by the Indiana board of pharmacy established by IC 25-26-13-3.

(5) The costs of the program.

(6) As part of the information to be completed in the data base and if available, an entry where a dispenser indicates that a patient is participating in a pain management contract with a designated practitioner.

(b) The board shall consider the recommendations of the committee concerning the INSPECT program.

(c) This subsection applies only to a retail pharmacy. A pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense ephedrine, pseudoephedrine, or a controlled substance may not

dispense ephedrine, pseudoephedrine, or a controlled substance to a person who is not personally known to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance unless the person taking possession of the ephedrine, pseudoephedrine, or controlled substance provides documented proof of the person's identification to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense ephedrine, pseudoephedrine, or a controlled substance.

(d) Beginning July 1, 2018, an individual who applies for or renews a controlled substance registration under IC 35-48-3-3(b) must also register or be registered with the INSPECT program.