SENATE BILL No. 408

DIGEST OF INTRODUCED BILL

Citations Affected: IC 35-48-7.

Synopsis: INSPECT program. Requires a dispenser of ephedrine, pseudoephedrine, or a controlled substance to transmit certain information to the INSPECT program on a real time basis beginning January 1, 2018. Provides that, to the extent considered appropriate by the state board of pharmacy (board), the INSPECT data base must be interoperable with other similar registries operated by federal and state governments. Adds an investigator for the state Medicaid fraud control unit to the list of persons who can receive certain confidential INSPECT program information. Requires a practitioner to obtain information about a patient from the INSPECT data base before prescribing ephedrine, pseudoephedrine, or a controlled substance to the patient. Requires the board to establish procedures for a patient or a patient's authorized representative to access the patient's report from the INSPECT program. (Current law allows a patient to access a report that has been included in the patient's medical file by a practitioner.) Provides that if a patient or patient's authorized representative disputes information in the patient's INSPECT report, the board shall investigate the claim and promptly revise any inaccurate information. Requires the board to seek and apply for grants and other money from federal agencies and other entities for the controlled substances data fund.

Effective: July 1, 2017.

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January 10, 2017, read first time and referred to Committee on Health and Provider Services.

Introduced

First Regular Session 120th General Assembly (2017)

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 2016 Regular Session of the General Assembly.

SENATE BILL No. 408

A BILL FOR AN ACT to amend the Indiana Code concerning criminal law and procedure.

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

SECTION 1. IC 35-48-7-8.1, AS AMENDED BY P.L.5-2016, SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2017]: 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,~~ **(A) Until December 31, 2017,** 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.

(B) Beginning January 1, 2018, on a real time basis.

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

(A) uploading to the INSPECT web site; **or**

~~(B) a computer diskette; or~~

~~(C) a CD-ROM disk;~~ **(B) another method** 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.

(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.

SECTION 2. IC 35-48-7-10.1, AS AMENDED BY P.L.5-2016, SECTION 11, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2017]: Sec. 10.1. (a) The INSPECT program must do the following:

(1) Create a data base for information required to be transmitted under section 8.1 of this chapter in the form required under rules adopted by the board, including search capability for the following:

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

(B) An ephedrine, pseudoephedrine, or a controlled substance recipient's or recipient representative's identification number.

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

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

(E) The dates ephedrine, pseudoephedrine, or a controlled substance are dispensed.

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

(G) The number of days of supply dispensed.

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

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

(J) Whether a prescription was transmitted to the pharmacist orally or in writing.

(K) An ephedrine, pseudoephedrine, or a controlled substance recipient's method of payment for the ephedrine, pseudoephedrine, or controlled substance dispensed.

(2) Provide the board with continuing twenty-four (24) hour a day online access to the data base.

(3) Secure the information collected and the data base maintained against access by unauthorized persons.

(4) To the extent considered appropriate by the board, the data base must be interoperable with other similar registries operated by federal and state governments.

(b) The board may not execute a contract with a vendor designated by the board to perform any function associated with the administration of the INSPECT program, unless the contract has been approved by the committee.

(c) The INSPECT program may gather prescription data from the Medicaid retrospective drug utilization review (DUR) program established under IC 12-15-35.

(d) The board may accept and designate grants, public and private financial assistance, and licensure fees to provide funding for the INSPECT program.

SECTION 3. IC 35-48-7-11.1, AS AMENDED BY THE TECHNICAL CORRECTIONS BILL OF THE 2017 GENERAL ASSEMBLY, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2017]: Sec. 11.1. (a) Information received by the INSPECT program under section 8.1 of this chapter is confidential.

(b) The board shall carry out a program to protect the confidentiality of the information described in subsection (a). The board may disclose the information to another person only under subsection (c), (d), or (g).

(c) The board may disclose confidential information described in subsection (a) to any person who is authorized to engage in receiving, processing, or storing the information.

(d) Except as provided in subsections (e) and (f), the board may release confidential information described in subsection (a) to the following persons:

(1) A member of the board or another governing body that licenses practitioners and is engaged in an investigation, an

adjudication, or a prosecution of a violation under any state or federal law that involves *ephedrine, pseudoephedrine, or* a controlled substance.

(2) An investigator for the consumer protection division of the office of the attorney general, **an investigator for the state Medicaid fraud control unit,** a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general, who is engaged in:

(A) an investigation;

(B) an adjudication; or

(C) a prosecution;

of a violation under any state or federal law that involves *ephedrine, pseudoephedrine, or* a controlled substance.

(3) A law enforcement officer who is an employee of:

(A) a local, state, or federal law enforcement agency; or

(B) an entity that regulates *ephedrine, pseudoephedrine, or* controlled substances or enforces *ephedrine, pseudoephedrine, or* controlled substances rules or laws in another state;

that is certified to receive *ephedrine, pseudoephedrine, or* controlled substance prescription drug information from the INSPECT program.

(4) A practitioner or practitioner's agent certified to receive information from the INSPECT program.

(5) *An ephedrine, pseudoephedrine, or* ~~a~~ controlled substance monitoring program in another state with which Indiana has established an interoperability agreement.

(6) The state toxicologist.

(7) A certified representative of the Medicaid retrospective and prospective drug utilization review program.

(8) A substance abuse assistance program for a licensed health care provider who:

(A) has prescriptive authority under IC 25; and

(B) is participating in the assistance program.

(9) An individual who holds a valid temporary medical permit issued under IC 25-22.5-5-4 or a temporary fellowship permit *issued* under IC 25-22.5-5-4.6.

(10) Beginning July 1, 2016, a county coroner conducting a medical investigation of the cause of death.

(e) Information provided to an individual under:

(1) subsection (d)(3) is limited to information:

(A) concerning an individual or proceeding involving the unlawful diversion or misuse of a schedule II, III, IV, or V

controlled substance; and

(B) that will assist in an investigation or proceeding; and

(2) subsection (d)(4) may be released only for the purpose of:

(A) providing medical or pharmaceutical treatment; or

(B) evaluating the need for providing medical or pharmaceutical treatment to a patient.

(f) Before the board releases confidential information under subsection (d), the applicant must be approved by the INSPECT program in a manner prescribed by the board.

(g) The board may release to:

(1) a member of the board or another governing body that licenses practitioners;

(2) an investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general; or

(3) a law enforcement officer who is:

(A) authorized by the state police department to receive *ephedrine, pseudoephedrine, or* controlled substance prescription drug information; and

(B) approved by the board to receive the type of information released;

confidential information generated from computer records that identifies practitioners who are prescribing or dispensing large quantities of a controlled substance.

(h) The information described in subsection (g) may not be released until it has been reviewed by:

(1) a member of the board who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data; or

(2) the board's designee;

and until that member or the designee has certified that further investigation is warranted. However, failure to comply with this subsection does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (i).

(i) An investigator or a law enforcement officer receiving confidential information under subsection (c), (d), or (g) may disclose the information to a law enforcement officer or an attorney for the office of the attorney general for use as evidence in the following:

(1) A proceeding under IC 16-42-20.

(2) A proceeding under any state or federal law that involves *ephedrine, pseudoephedrine, or* a controlled substance.

(3) A criminal proceeding or a proceeding in juvenile court that involves *ephedrine, pseudoephedrine, or* a controlled substance.

(j) The board may compile statistical reports from the information described in subsection (a). The reports must not include information that identifies any practitioner, ultimate user, or other person administering *ephedrine, pseudoephedrine, or* a controlled substance. Statistical reports compiled under this subsection are public records.

(k) ~~Except as provided in IC 25-22.5-13, this section may not be construed to require~~ A practitioner ~~to~~ **shall** obtain information about a patient from the data base **before prescribing ephedrine, pseudoephedrine, or a controlled substance to the patient.**

(l) A practitioner *who checks the INSPECT program for the available data on a patient* is immune from civil liability for an injury, death, or loss to a person solely due to a practitioner:

(1) seeking ~~*or not seeking*~~ information from the INSPECT program; *and*

(2) in good faith using the information for the treatment of the patient.

The civil immunity described in this subsection does not extend to a practitioner if the practitioner receives information directly from the INSPECT program and then negligently misuses this information. This subsection does not apply to an act or omission that is a result of gross negligence or intentional misconduct.

(m) The board may review the records of the INSPECT program. If the board determines that a violation of the law may have occurred, the board shall notify the appropriate law enforcement agency or the relevant government body responsible for the licensure, regulation, or discipline of practitioners authorized by law to prescribe controlled substances.

(n) A practitioner who in good faith discloses information based on a report from the INSPECT program to a law enforcement agency is immune from criminal or civil liability. A practitioner that discloses information to a law enforcement agency under this subsection is presumed to have acted in good faith.

(o) A practitioner's agent may act as a delegate and check INSPECT program reports on behalf of the practitioner.

(p) **The board shall establish procedures for** *a patient* ~~*may*~~ **or a patient's authorized representative to** *access* ~~*a*~~ **the patient's** *report from the INSPECT program.* ~~*that has been included in the patient's medical file by a practitioner.*~~ **If a patient or the patient's authorized representative disputes information in the patient's INSPECT report, the board shall investigate the claim and promptly revise**

any inaccurate information.

SECTION 4. IC 35-48-7-13.1, AS AMENDED BY P.L.112-2014, SECTION 39, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2017]: Sec. 13.1. (a) The controlled substances data fund is established to fund the administration of the INSPECT program. The fund shall be administered by the Indiana professional licensing agency.

(b) Expenses of administering the fund shall be paid from money in the fund. The fund consists of grants, public and private financial assistance, and the controlled substances registration fees imposed under rules adopted under IC 35-48-3-1.

(c) The treasurer of state shall invest the money in the fund not currently needed to meet the obligations of the fund in the same manner as other public money may be invested.

(d) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

(e) The board shall seek and apply for grants and other money for the fund from federal agencies and other entities.