February 26, 2018

ENGROSSED
SENATE BILL No. 221

DIGEST OF SB 221 (Updated February 26, 2018 12:07 pm - DI 77)

Citations Affected: IC 35-48.

Synopsis: INSPECT program. Allows a dispenser of ephedrine, pseudoephedrine, or a controlled substance to transmit certain information to the INSPECT program by any electronic method that meets specifications prescribed by the state board of pharmacy (board). Provides that, to the extent considered appropriate by the board, the INSPECT data base must be interoperable with other similar registries operated by federal and state governments. Requires the following practitioners to obtain information about a patient from the data base before prescribing an opioid or benzodiazepine to the patient: (1) A practitioner who has had the information from the data base integrated into the patient's electronic health records. (2) Beginning January 1, 2019, a practitioner who provides services to the patient in the emergency department of a hospital or a pain management clinic. (3) Beginning January 1, 2020, a practitioner who provides services to the

(Continued next page)

Effective: July 1, 2018.

Houchin, Charbonneau, Zakas,
Lanane, Mrvan, Zay, Holdman,
Alting, Randolph Lonnie M
(HOUSE SPONSORS — SMALTZ, ZENT, SHACKLEFORD, BROWN C)

January 3, 2018, read first time and referred to Committee on Health and Provider Services.
January 18, 2018, amended, reported favorably — Do Pass.
January 22, 2018, read second time, ordered engrossed. Engrossed.
January 25, 2018, read third time, passed. Yeas 47, nays 1.

HOUSE ACTION

February 6, 2018, read first time and referred to Committee on Public Health.
February 26, 2018, amended, reported — Do Pass.

patient in a hospital. (4) Beginning January 1, 2021, all practitioners. Provides that a practitioner is not required to obtain information about a patient who is subject to a pain management contract from the INSPECT data base more than once every 90 days. Removes lapsed provisions. Provides that beginning January 1, 2019, a practitioner who is permitted to distribute, dispense, prescribe, conduct research with respect to, or administer ephedrine, pseudoephedrine, or a controlled substance in the course of the practitioner's professional practice or research must be certified to receive information from the INSPECT program. Allows a practitioner to request a waiver from the requirement of checking the data base before prescribing an opioid or benzodiazepine if the practitioner does not have access to the Internet at the practitioner's place of business. Requires the Indiana state board of pharmacy to: (1) establish a process for a practitioner to request a waiver; (2) determine whether to grant a practitioner's request for a waiver; and (3) issue a waiver when the board determines a waiver is warranted.

February 26, 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.

ENGROSSED
SENATE BILL No. 221

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 35-48-7-5.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: **Sec. 5.5. (a) As used in this chapter, "pain management clinic" means a publicly or privately owned facility that primarily engages in the treatment of pain or pain management through prescribing controlled substances.**

(b) The term does not include the following:

(1) A hospital licensed under 16-21, including a facility owned by the hospital or an office of a hospital employed physician.

(2) An accredited school, college, university, or other educational institution or program that is related to providing instruction to individuals preparing to practice as a dentist, physician, physician assistant, nurse, optometrist, podiatrist, or veterinarian.

(3) A hospice program licensed under IC 16-25-3.

(4) An ambulatory outpatient surgical center licensed under IC 16-21-2.

(5) A long term care facility licensed under IC 16-28-2.

SECTION 2. 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; **or**

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

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

(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.

SECTION 3. IC 35-48-7-10.1, AS AMENDED BY P.L.5-2016,

SECTION 11, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: 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.

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

(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.

(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 4. IC 35-48-7-11.1, AS AMENDED BY P.L.164-2017, SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: 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, 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 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.

(11) The management performance hub established by Indiana Executive Order 14-06 and continued by Executive Order 17-09.

(12) The state epidemiologist under the state department of health.

(e) Information provided to a person 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;

(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; and

(3) subsection (d)(11) must be released to the extent disclosure of the information is not prohibited by applicable federal law.

(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 subsection (q) and in addition to any requirements** provided in IC 25-22.5-13, ~~this section may not be construed to require a practitioner to~~ **the following practitioners shall** obtain information about a patient from the data base **before prescribing an opioid or benzodiazepine to the patient:**

(1) A practitioner who has had the information from the data base integrated into the patient's electronic health records.

(2) Beginning January 1, 2019, a practitioner who provides services to the patient in:

(A) the emergency department of a hospital licensed under IC 16-21; or

(B) a pain management clinic.

(3) Beginning January 1, 2020, a practitioner who provides services to the patient in a hospital licensed under IC 16-21.

(4) Beginning January 1, 2021, all practitioners.

However, a practitioner is not required to obtain information about a patient who is subject to a pain management contract from the data base more than once every ninety (90) days.

(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 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) A patient may access a report from the INSPECT program that has been included in the patient's medical file by a practitioner.

(q) A practitioner is not required under subsection (k) to obtain information about a patient from the data base before prescribing an opioid or benzodiazepine if the practitioner has obtained a waiver from the board because the practitioner does not have access to the Internet at the practitioner's place of business.

SECTION 5. IC 35-48-7-11.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: **Sec. 11.3. Beginning January 1, 2019, a practitioner who is permitted to distribute, dispense, prescribe,**

conduct research with respect to, or administer ephedrine, pseudoephedrine, or a controlled substance in the course of the practitioner's professional practice or research in the United States must be certified under section 11.1(d)(4) of this chapter to receive information from the INSPECT program.

SECTION 6. IC 35-48-7-12.1, AS AMENDED BY P.L.5-2016, SECTION 13, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: Sec. 12.1. (a) The board shall adopt rules under IC 4-22-2 to implement this chapter, including the following:

(1) Information collection and retrieval procedures for the INSPECT program, including the controlled substances to be included in the program required under section 8.1 of this chapter.

(2) Design for the creation of the data base required under section 10.1 of this chapter.

(3) Requirements for the development and installation of online electronic access by the board to information collected by the INSPECT program.

(4) Identification of emergency situations or other circumstances in which a practitioner may prescribe, dispense, and administer a prescription drug specified in section 8.1 of this chapter without a written prescription or on a form other than a form specified in section 8.1(a)(4) of this chapter.

(5) Requirements for a practitioner providing treatment for a patient at an opioid treatment program operating under IC 12-23-18 to check the INSPECT program:

(A) before initially prescribing ephedrine, pseudoephedrine, or a controlled substance to a patient; and

(B) periodically during the course of treatment that uses ephedrine, pseudoephedrine, or a controlled substance.

(b) The board may:

(1) set standards for education courses for individuals authorized to use the INSPECT program;

(2) identify treatment programs for individuals addicted to controlled substances monitored by the INSPECT program; and

(3) work with impaired practitioner associations to provide intervention and treatment.

(c) The executive director of the Indiana professional licensing agency may hire a person to serve as the director of the INSPECT program, with the approval of the chairperson of the board.

(d) The board shall do the following:

(1) Establish a procedure for a practitioner to request a waiver from the requirements of section 11.1(k) of this

chapter if the practitioner does not have access to the Internet at the practitioner's place of business.

(2) Review a practitioner's written request for a waiver from the requirements of section 11.1(k) of this chapter and determine whether the practitioner should be granted a waiver.

(3) Upon determination by the board under subdivision (2) that a practitioner should be granted a waiver under this subsection, issue the practitioner a waiver.

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 221, 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 32, reset in roman "Except as".

Page 7, line 32, delete "In" and insert "**provided in subsection (q) and in**".

Page 8, between lines 30 and 31, begin a new paragraph and insert:

"**(q) A practitioner is not required under subsection (k) to obtain information about a patient from the data base before prescribing an opioid or benzodiazepine if the practitioner has obtained a waiver from the board because the practitioner does not have access to the Internet at the practitioner's place of business.**".

Page 8, after line 39, begin a new paragraph and insert:

"SECTION 6. IC 35-48-7-12.1, AS AMENDED BY P.L.5-2016, SECTION 13, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2018]: Sec. 12.1. (a) The board shall adopt rules under IC 4-22-2 to implement this chapter, including the following:

(1) Information collection and retrieval procedures for the INSPECT program, including the controlled substances to be included in the program required under section 8.1 of this chapter.

(2) Design for the creation of the data base required under section 10.1 of this chapter.

(3) Requirements for the development and installation of online electronic access by the board to information collected by the INSPECT program.

(4) Identification of emergency situations or other circumstances in which a practitioner may prescribe, dispense, and administer a prescription drug specified in section 8.1 of this chapter without a written prescription or on a form other than a form specified in section 8.1(a)(4) of this chapter.

(5) Requirements for a practitioner providing treatment for a patient at an opioid treatment program operating under IC 12-23-18 to check the INSPECT program:

(A) before initially prescribing ephedrine, pseudoephedrine, or a controlled substance to a patient; and

(B) periodically during the course of treatment that uses ephedrine, pseudoephedrine, or a controlled substance.

(b) The board may:

(1) set standards for education courses for individuals authorized to use the INSPECT program;

(2) identify treatment programs for individuals addicted to controlled substances monitored by the INSPECT program; and

(3) work with impaired practitioner associations to provide intervention and treatment.

(c) The executive director of the Indiana professional licensing agency may hire a person to serve as the director of the INSPECT program, with the approval of the chairperson of the board.

(d) The board shall do the following:

(1) Establish a procedure for a practitioner to request a waiver from the requirements of section 11.1(k) of this chapter if the practitioner does not have access to the Internet at the practitioner's place of business.

(2) Review a practitioner's written request for a waiver from the requirements of section 11.1(k) of this chapter and determine whether the practitioner should be granted a waiver.

(3) Upon determination by the board under subdivision (2) that a practitioner should be granted a waiver under this subsection, issue the practitioner a waiver.".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 221 as introduced.)

CHARBONNEAU, Chairperson

Committee Vote: Yeas 10, Nays 0.

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred Senate Bill 221, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 8, between lines 4 and 5, begin a new line blocked left and insert:

"**However, a practitioner is not required to obtain information**

about a patient who is subject to a pain management contract from the data base more than once every ninety (90) days.".

and when so amended that said bill do pass.

(Reference is to SB 221 as printed January 19, 2018.)

KIRCHHOFER

Committee Vote: yeas 9, nays 0.