Second Regular Session 118th General Assembly (2014)

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 2013 Regular Session and 2013 First Regular Technical Session of the General Assembly.

HOUSE ENROLLED ACT No. 1218

AN ACT to amend the Indiana Code concerning human services.

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

SECTION 1. IC 12-7-2-67.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: **Sec. 67.5. "Dispense", for purposes of IC 12-23-18-8, has the meaning set forth in IC 12-23-18-8(a).**

SECTION 2. IC 12-23-18-2.5, AS ADDED BY P.L.116-2008, SECTION 5, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: Sec. 2.5. (a) An opioid treatment program must periodically and randomly test, including before receiving treatment, a patient for the following during the patient's treatment by the program:

(1) Methadone.
(2) Cocaine.
(3) Opiates.
(4) Amphetamines.
(5) Barbiturates.
(6) Tetrahydrocannabinol.
(7) Benzodiazepines.
(8) Any other suspected or known drug that may have been abused by the patient.

(b) If a patient tests positive under a test described in subsection (a)

for:

(1) a controlled substance other than a drug for which the patient has a prescription or that is part of the patient's treatment plan at the opioid treatment program; or

(2) an illegal drug other than the drug that is part of the patient's treatment plan at the opioid treatment program;

the opioid treatment program and the patient must comply with the requirements under subsection (c).

(c) If a patient tests positive under a test for a controlled substance or illegal drug that is not allowed under subsection ~~(b),~~ **(a),** the following conditions must be met:

(1) The opioid treatment program must refer the patient to the onsite physician for a clinical evaluation that must be conducted not more than ten (10) days after the date of the patient's positive test. The physician shall consult with medical and behavioral staff to conduct the evaluation. The clinical evaluation must recommend a remedial action for the patient that may include discharge from the opioid treatment program or amending the treatment plan to require a higher level of supervision.

(2) The opioid treatment program may not allow the patient to take any opioid treatment medications from the treatment facility until the patient has completed a clinical assessment under subdivision (1) and has passed a random test. The patient must report to the treatment facility daily, except when the facility is closed, until the onsite physician, after consultation with the medical and behavioral staff, determines that daily treatment is no longer necessary.

(3) The patient must take a weekly random test until the patient passes a test under subsection ~~(b).~~ **(a).**

(d) An opioid treatment program must conduct all tests required under this section in an observed manner to assure that a false sample is not provided by the patient.

SECTION 3. IC 12-23-18-5, AS AMENDED BY P.L.116-2008, SECTION 8, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: Sec. 5. (a) The division shall adopt rules under IC 4-22-2 to establish the following:

(1) Standards for operation of an opioid treatment program in Indiana, including the following requirements:

(A) An opioid treatment program shall obtain prior authorization from the division for any patient receiving more than ~~fourteen (14)~~ **seven (7)** days of opioid treatment medications at one (1) time **and the division may approve**

the authorization only under the following circumstances:

(i) A physician licensed under IC 25-22.5 has issued an order for the opioid treatment medication.

(ii) The patient has not tested positive under a drug test for a drug for which the patient does not have a prescription for a period of time set forth by the division.

(iii) The opioid treatment program has determined that the benefit to the patient in receiving the take home opioid treatment medication outweighs the potential risk of diversion of the take home opioid treatment medication.

(B) Minimum requirements for a licensed physician's regular:

(i) physical presence in the opioid treatment facility; and

(ii) physical evaluation and progress evaluation of each opioid treatment program patient.

(C) Minimum staffing requirements by licensed and unlicensed personnel.

(D) Clinical standards for the appropriate tapering of a patient on and off of an opioid treatment medication.

(2) A requirement that, not later than February 28 of each year, a current diversion control plan that meets the requirements of 21 CFR Part 291 and 42 CFR Part 8 be submitted for each opioid treatment facility.

(3) Fees to be paid by an opioid treatment program for deposit in the fund for annual certification under this chapter as described in section 3 of this chapter.

The fees established under this subsection must be sufficient to pay the cost of implementing this chapter.

(b) The division shall conduct an annual onsite visit of each opioid treatment program facility to assess compliance with this chapter.

(c) Not later than April 1 of each year, the division shall report to the general assembly in electronic format under IC 5-14-3 the number of prior authorizations that were approved under subsection (a)(1)(A) in the previous year and the time frame for each approval.

SECTION 4. IC 12-23-18-7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: **Sec. 7. (a) The division shall adopt rules under IC 4-22-2 to establish standards and protocols for opioid treatment programs to do the following:**

(1) Assess new opioid treatment program patients to determine the most effective opioid treatment medications to

start the patient's opioid treatment.

(2) Ensure that each patient voluntarily chooses maintenance treatment and that relevant facts concerning the use of opioid treatment medications are clearly and adequately explained to the patient.

(3) Have appropriate opioid treatment program patients who are receiving methadone for opioid treatment move to receiving other approved opioid treatment medications.

(b) An opioid treatment program shall follow the standards and protocols adopted under subsection (a) for each opioid treatment program patient.

(c) Subject to subsection (a), an opioid treatment program may use any of the following medications as an alternative for methadone for opioid treatment:

(1) Buprenorphine.

(2) Buprenorphine combination products containing naloxone.

(3) Any other medication that has been approved by:

(A) the federal Food and Drug Administration for use in the treatment of opioid addiction; and

(B) the division under subsection (e).

(d) Before starting a patient on a new opioid treatment medication, the opioid treatment program shall explain to the patient the potential side effects of the new medication.

(e) The division may adopt rules under IC 4-22-2 to provide for other medications as alternatives to methadone that may be used under subsection (a).

SECTION 5. IC 12-23-18-8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: **Sec. 8. (a) As used in this section, "dispense" means to deliver a controlled substance to an ultimate user.**

(b) Subject to the federal patient confidentiality requirements under 42 CFR Part 2, when an opioid treatment program dispenses a controlled substance designated by the Indiana board of pharmacy under IC 35-48-2-5 through 35-48-2-10, the opioid treatment program shall provide the following information upon request from the division:

(1) The medications dispensed by the program.

(2) The medication delivery process, which includes whether the medication was in liquid, film, or another form.

(3) The number of doses dispensed of each medication.

(4) The dosage quantities for each medication.

(5) The number of patients receiving take home medications.

(6) The number of days of supply dispensed.

(7) Patient demographic information for each medication, including gender, age, and time in treatment.

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

(c) An opioid treatment program shall provide the information required under this section to the division in a manner prescribed by the division.

(d) The division shall annually report the information collected under this section to the legislative council in an electronic format under IC 5-14-6 not later than October 1.

SECTION 6. IC 16-18-2-199 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: Sec. 199. "Legend drug", for purposes of IC 16-42, means a drug that is:

(1) subject to 21 U.S.C. 353(b)(1); ~~or~~

(2) listed in the Prescription Drug Product List as:

(A) published in United States Department of Health and Human Services Approved Drug Products with Therapeutic Equivalence Evaluations, Tenth Edition, (1990); and

(B) revised in United State Department of Health and Human Services, Approved Drug Products with Therapeutic Equivalence Evaluations, Cumulative Supplement to the Tenth Edition, Number 10 (1990); **or**

(3) insulin.

SECTION 7. IC 16-39-2-8 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: Sec. 8. **(a)** The court may order the release of the patient's mental health record without the patient's consent upon the showing of good cause following a hearing under IC 16-39-3 or in a proceeding under IC 31-30 through IC 31-40 following a hearing held under the Indiana Rules of Trial Procedure.

(b) A provider shall, upon the request of a court that has committed a patient under IC 12-26-7, IC 12-26-8, IC 35-36-2-4, or IC 35-36-3, release to the court any information from the patient's mental health record that is required by the Federal Bureau of Investigation for transmission to NICS (as defined in IC 35-47-2.5-2.5) in accordance with IC 33-24-6-3.

SECTION 8. IC 16-42-19-29 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: **Sec. 29. A legend drug that is composed wholly or partly of insulin may be sold for retail sale by a pharmacy only to an individual who possesses a prescription**

from one (1) of the following:

(1) A physician licensed under IC 25-22.5.

(2) A veterinarian licensed to practice veterinary medicine in Indiana.

(3) An advanced practice nurse who meets the requirements of IC 25-23-1-19.5.

(4) A physician assistant licensed under IC 25-27.5 who is delegated prescriptive authority under IC 25-27.5-5-6.

SECTION 9. IC 35-48-7-8.1, AS AMENDED BY P.L.152-2012, SECTION 14, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 8.1. (a) The board shall provide for a controlled substance prescription monitoring program that includes the following components:

(1) Each time 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 controlled substance recipient's name.

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

(C) The controlled substance recipient's date of birth.

(D) The national drug code number of the controlled substance dispensed.

(E) The date the controlled substance is dispensed.

(F) The quantity of the 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 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 a controlled substance is dispensed.

(C) Beginning January 1, 2016, and thereafter, not more

than twenty-four (24) hours after the date on which a controlled substance is dispensed.

(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 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) This subsection applies only to a retail pharmacy. A pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance may not dispense 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 controlled substance provides documented proof of the person's identification to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance.

SECTION 10. IC 35-48-7-11.1, AS AMENDED BY P.L.84-2010, SECTION 99, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: 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 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 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 controlled substances or enforces controlled substances rules or laws in another state;

that is certified to receive **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) 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.

(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 ~~the type of~~ **controlled substance prescription drug** information; ~~released;~~ 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 a controlled substance.

(3) A criminal proceeding or a proceeding in juvenile court that involves 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 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 obtain information about a patient from the data base.

(l) A practitioner is immune from civil liability for an injury, death, or loss to a person solely due to a practitioner seeking or not seeking information from the INSPECT program. 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.

SECTION 11. IC 35-48-7-12.1, AS AMENDED BY P.L.42-2011, SECTION 77, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: 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 a controlled substance to a patient; and

(B) periodically during the course of treatment that uses 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.

SECTION 12. IC 35-48-7-16 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: **Sec. 16. (a) Before October 1, 2014, the Indiana professional licensing agency shall:**

(1) study the impact of including all prescription drugs in the INSPECT program; and

(2) report the findings to the legislative council in an electronic format under IC 5-14-6.

(b) The study under subsection (a) must include the following:

(1) The efficacy of including drugs other than controlled substances in the INSPECT program.

(2) Recommended parameters for the inclusion of drugs other than controlled substances.

(3) Analysis of any security concerns related to patient and provider privacy.

(4) Technology requirements.

(5) Regulatory impact analysis.

(6) Fiscal impact analysis.

(c) The:

(1) state department of health;

(2) office of the secretary of family and social services;

(3) department of homeland security; and

(4) Indiana office of technology (IC 4-13.1-2);

shall assist the Indiana professional licensing agency with the study required by this section.

SECTION 13. [EFFECTIVE JULY 1, 2014] **(a) During the 2014 interim of the general assembly, the legislative council shall assign to an appropriate interim committee the study of the integrity and security of the INSPECT program (IC 35-48-7). The interim committee shall make findings and recommendations, including**

recommendations to the Indiana professional licensing agency established by IC 25-1-5-3 to ensure that data collected by the INSPECT program may be used only for lawful purposes.

(b) This SECTION expires January 1, 2015.

SECTION 14. [EFFECTIVE UPON PASSAGE] **(a) During the 2014 interim of the general assembly, the legislative council shall assign to an appropriate interim committee the study of whether opioid treatment programs should be prohibited from allowing patients to take home a multiple day supply of opioid treatment medication.**

(b) This SECTION expires December 31, 2014.

SECTION 15. **An emergency is declared for this act.**

Speaker of the House of Representatives

President of the Senate

President Pro Tempore

Governor of the State of Indiana

Date: _____ Time: _____