CONFERENCE COMMITTEE REPORT
DIGEST FOR ESB 246

Citations Affected: IC 12-15-35-51; IC 25-22.5; IC 35-31.5-2-224; IC 35-48.

Synopsis: Controlled substances Conference committee report for Engrossed Senate Bill 246. Defines "owner" for purposes of requiring an owner that employs or contracts with individuals to dispense controlled substances to, beginning January 1, 2014, maintain a controlled substance registration. Beginning January 1, 2014, allows the attorney general to petition the court to obtain an injunction against an owner that violates the controlled substance registration and control laws. Requires the medical licensing board to adopt emergency rules and permanent rules within a specified period concerning: (1) standards and procedures for the attorney general to follow in accessing physicians' records and inventory; and (2) standards and protocol for the prescribing of controlled substances. During the 2013 legislative interim, requires the health finance commission to study: (1) issues concerning pharmacy programs designed to take back and dispose of old and expired prescription drugs; and (2) the use of methadone and opioids in treatment programs and clinic settings. Requires the division on mental health and addiction to provide the health finance commission specified information concerning opioid treatment in Indiana. During the 2013 legislative interim, requires the commission on mental health and addiction to study issues concerning treatment and recovery from prescription drug use addiction. Resolves a conflict and corrects a cross reference. **(This conference committee report: Fixes a conflict between this bill and Senate Bill 414, and corrects a cross reference in Senate Enrolled Act 536.)**

Effective: Upon passage; July 1, 2013.

CONFERENCE COMMITTEE REPORT

MADAM PRESIDENT:

Your Conference Committee appointed to confer with a like committee from the House upon Engrossed House Amendments to Engrossed Senate Bill No. 246 respectfully reports that said two committees have conferred and agreed as follows to wit:

that the Senate recede from its dissent from all House amendments and that the Senate now concur in all House amendments to the bill and that the bill be further amended as follows:

Delete everything after the enacting clause and insert the following:

SECTION 1. IC 12-15-35-51, AS ADDED BY P.L.36-2009, SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 51. (a) As used in this section, "advisory committee" refers to the mental health Medicaid quality advisory committee established by subsection (b).

(b) The mental health Medicaid quality advisory committee is established. The advisory committee consists of the following members:

(1) The director of the office or the director's designee, who shall serve as chairperson of the advisory committee.

(2) The director of the division of mental health and addiction or the director's designee.

(3) A representative of a statewide mental health advocacy organization.

(4) A representative of a statewide mental health provider organization.

(5) A representative from a managed care organization that participates in the state's Medicaid program.

(6) A member with expertise in psychiatric research representing an academic institution.

(7) A pharmacist licensed under IC 25-26.

(8) The commissioner of the department of correction or the commissioner's designee.

The governor shall make the appointments for a term of four (4) years under subdivisions (3) through (7) and fill any vacancy on the advisory committee.

(c) The office shall staff the advisory committee. The expenses of the advisory committee shall be paid by the office.

(d) Each member of the advisory committee who is not a state employee is entitled to the minimum salary per diem provided by IC 4-10-11-2.1(b). The member is also entitled to reimbursement for traveling expenses as provided under IC 4-13-1-4 and other expenses actually incurred in connection with the member's duties as provided in the state policies and procedures established by the Indiana department of administration and approved by the budget agency.

(e) Each member of the advisory committee who is a state employee is entitled to reimbursement for traveling expenses as provided under IC 4-13-1-4 and other expenses actually incurred in connection with the member's duties as provided in the state policies and procedures established by the Indiana department of administration and approved by the budget agency.

(f) The affirmative votes of a majority of the voting members appointed to the advisory committee are required by the advisory committee to take action on any measure.

(g) The advisory committee shall advise the office and make recommendations concerning the **clinical use of mental health and addiction medications, including the** implementation of IC 12-15-35.5-7(c), and consider the following:

(1) Peer reviewed medical literature.

(2) Observational studies.

(3) Health economic studies.

(4) Input from physicians and patients.

(5) Any other information determined by the advisory committee to be appropriate.

(h) The office shall report recommendations made by the advisory committee to the drug utilization review board established by section 19 of this chapter.

(i) The office shall report the following information to the select joint commission on Medicaid oversight established by IC 2-5-26-3:

(1) The advisory committee's advice and recommendations made under this section.

(2) The number of restrictions implemented under IC 12-15-35.5-7(c) and the outcome of each restriction.

(3) The transition of individuals who are aged, blind, or disabled to the risk based managed care program. This information shall also be reported to the health finance commission established by IC 2-5-23-3.

(4) Any decision by the office to change the health care delivery system in which Medicaid is provided to recipients.

(j) Notwithstanding subsection (b), the initial members appointed to the advisory committee under this section are appointed for the

following terms:

(1) Individuals appointed under subsection (b)(3) and (b)(4) are appointed for a term of four (4) years.

(2) An individual appointed under subsection (b)(5) is appointed for a term of three (3) years.

(3) An individual appointed under subsection (b)(6) is appointed for a term of two (2) years.

(4) An individual appointed under subsection (b)(7) is appointed for a term of one (1) year.

This subsection expires December 31, 2013.

SECTION 2. IC 25-22.5-2-7, AS AMENDED BY SEA 414, SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 7. (a) The board shall do the following:

(1) Adopt rules and forms necessary to implement this article that concern, but are not limited to, the following areas:

(A) Qualification by education, residence, citizenship, training, and character for admission to an examination for licensure or by endorsement for licensure.

(B) The examination for licensure.

(C) The license or permit.

(D) Fees for examination, permit, licensure, and registration.

(E) Reinstatement of licenses and permits.

(F) Payment of costs in disciplinary proceedings conducted by the board.

(2) Administer oaths in matters relating to the discharge of ~~its~~ **the board's** official duties.

(3) Enforce this article and assign to the personnel of the agency duties as may be necessary in the discharge of the board's duty.

(4) Maintain, through the agency, full and complete records of all applicants for licensure or permit and of all licenses and permits issued.

(5) Make available, upon request, the complete schedule of minimum requirements for licensure or permit.

(6) Issue, at the board's discretion, a temporary permit to an applicant for the interim from the date of application until the next regular meeting of the board.

(7) Issue an unlimited license, a limited license, or a temporary medical permit, depending upon the qualifications of the applicant, to any applicant who successfully fulfills all of the requirements of this article.

(8) Adopt rules establishing standards for the competent practice of medicine, osteopathic medicine, or any other form of practice regulated by a limited license or permit issued under this article.

(9) Adopt rules regarding the appropriate prescribing of Schedule III or Schedule IV controlled substances for the purpose of weight reduction or to control obesity.

(10) Adopt rules establishing standards for office based procedures that require moderate sedation, deep sedation, or general anesthesia.

(11) Adopt rules or protocol establishing the following:

(A) An education program to be used to educate women with high breast density.

(B) Standards for providing an annual screening or diagnostic test for a woman who is at least forty (40) years of age and who has been determined to have high breast density.

As used in this subdivision, "high breast density" means a condition in which there is a greater amount of breast and connective tissue in comparison to fat in the breast.

(12) Adopt rules establishing standards and protocols for the prescribing of controlled substances.

(b) The board may adopt rules that establish:

(1) certification requirements for child death pathologists;

(2) an annual training program for child death pathologists under IC 16-35-7-3(b)(2); and

(3) a process to certify a qualified child death pathologist.

SECTION 3. IC 25-22.5-13 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]:

Chapter 13. Controlled Substance Rules

Sec. 1. (a) Before November 1, 2013, the board shall adopt emergency rules in the manner provided under IC 4-22-2-37.1 to establish standards and procedures to do the following:

(1) Receive and review petitions from the attorney general seeking board authorization to examine a physician's records and controlled substances inventory and materials to investigate the physician's controlled substances prescribing practices.

(2) Authorize, where appropriate, the attorney general to examine records, materials, and inventory relating to the physician's controlled substance prescribing practices.

(3) Provide safeguards and protections for physicians against unreasonable and oppressive examination authorizations and actions taken to carry out the authorizations, including limitations on interference with regular practice operations and other appropriate due process provisions.

(b) Before November 1, 2014, the board shall adopt permanent rules under IC 4-22-2 to establish permanent rules for the standards and procedures described in subsection (a).

(c) An emergency rule adopted under subsection (a) remains in effect until the effective date of the permanent rules adopted under subsection (b).

(d) The rules adopted under this section do not abrogate or eliminate the attorney general's investigative authority under IC 4-6-3-3, IC 4-6-10-3, IC 25-1-7-4, or any other applicable statute or rule.

Sec. 2. (a) Consistent with standard medical practices in pain management treatment, the medical licensing board shall:

(1) before November 1, 2013, adopt emergency rules in the manner provided in IC 4-22-2-37.1; and

(2) before November 1, 2014, adopt rules under IC 4-22-2;

to establish standards and protocols for the prescribing of

controlled substances.

(b) An emergency rule adopted under subsection (a)(1) remains in effect until the effective date of the permanent rule adopted under subsection (a)(2).

Sec. 3. The state board of pharmacy or any licensing board, commission, or agency that controls, authorizes, or oversees controlled substance registrations under IC 35-48-3 shall adopt rules necessary to complement the rules adopted by the medical licensing board under this chapter.

Sec. 4. A board, commission, or agency required to adopt rules under this chapter may adopt emergency rules in the manner provided under IC 4-22-2-37.1 for the same purposes.

Sec. 5. For purposes of Executive Order 13-03, the predominate purpose and effect of rules adopted under this chapter is to address emergency matters of health and safety.

SECTION 4. IC 35-31.5-2-224, AS ADDED BY P.L.114-2012, SECTION 67, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 224. (a) "Owner", for purposes of IC 35-43-1-3, has the meaning set forth in IC 35-43-1-3(a).

(b) "Owner", for purposes of IC 35-48-3, has the meaning set forth in IC 35-48-3-1.5.

~~(b)~~ **(c)** "Owner", for purposes of IC 35-49, has the meaning set forth in IC 35-49-1-6.

SECTION 5. IC 35-48-3-1.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 1.5. (a) This section is effective beginning January 1, 2014.**

(b) As used in this chapter, "owner" means a person that employs or contracts with at least one (1) individual to dispense a controlled substance in an office, facility, clinic, or location owned or controlled by the person. The term does not include the following:

(1) A person licensed by a board listed in IC 25-1-9.

(2) A dentist licensed under IC 25-14.

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

(4) An optometrist licensed under IC 25-24.

(5) A podiatrist licensed under IC 25-29.

(6) A community mental health center certified under IC 12-21-2-3(5)(C).

(7) A private mental health institution or private psychiatric hospital licensed under IC 12-25.

(8) A hospital or ambulatory outpatient surgical center licensed under IC 16-21.

(9) A hospice licensed under IC 16-25.

(10) A home health agency licensed under IC 16-27-1.

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

(12) A rural health clinic (as defined in 42 U.S.C. 1396d(l)(1)).

(13) A federally qualified health center (as defined in 42 U.S.C. 1396d(l)(2)(B)).

(14) A pharmacist or pharmacy licensed under IC 25-26.

(15) A community health center (as defined in IC 34-18-2-9).

(16) An affiliate, member, partner, or subsidiary of any person described in subdivisions (6) through (15).

(17) A:

(A) corporation;

(B) partnership;

(C) joint venture;

(D) limited liability company; or

(E) professional corporation;

or any other entity in which more than fifty percent (50%) of the owners, shareholders, partners, or members are persons listed in subdivisions (1) through (16).

SECTION 6. IC 35-48-3-3 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: 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 ~~its~~ **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 ~~its~~ **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.

~~(c)~~ **(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.

~~(d)~~ **(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 ~~he~~ **the agent or employee** is acting in the usual course of ~~his~~ **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.

~~(e)~~ **(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.

~~(f)~~ **(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.

~~(g)~~ **(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.

SECTION 7. IC 35-48-4-11.5 AS ADDED BY SEA 536-2013, SECTION 24, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 11.5. (a) As used in this section, "synthetic drug lookalike substance" has the meaning set forth in ~~IC 35-31.5-2-321.5(a)(3).~~ **IC 35-31.5-2-321.5(a)(2).**

(b) A person who possesses a synthetic drug or synthetic drug lookalike substance commits possession of a synthetic drug or synthetic drug lookalike substance, a Class B infraction.

(c) A person who knowingly or intentionally possesses a synthetic drug or synthetic drug lookalike substance commits possession of a synthetic drug or synthetic drug lookalike substance, a Class A misdemeanor. However, the offense is a Class D felony if the person has a prior unrelated conviction under this section or under section 10.5 of this chapter.

SECTION 8. [EFFECTIVE JULY 1, 2013] **(a) As used in this SECTION, "commission" refers to the health finance commission established by IC 2-5-23-3.**

(b) During the 2013 legislative interim, the commission shall study issues concerning pharmacy programs designed to take back and dispose of old and expired prescription drugs. The commission shall examine existing obstacles that pharmacies encounter in operating a prescription drug take-back program and recommend solutions that would allow consumers to dispose of old and expired prescription drugs at local pharmacies without difficulty.

(c) This SECTION expires December 31, 2013.

SECTION 9. [EFFECTIVE JULY 1, 2013] **(a) As used in this SECTION, "commission" refers to the Indiana commission on mental health and addiction established by IC 12-21-6.5-2.**

(b) During the 2013 legislative interim, the commission shall study issues concerning treatment and recovery from prescription

drug use addiction. The commission shall study and make recommendations concerning the following:

(1) Use of the Indiana health care professional recruitment and retention fund established by IC 16-46-5-8 to provide loan repayment for student loans incurred by addiction professionals.

(2) Criteria for Medicaid reimbursement for detoxification and rehabilitation services for addiction treatment.

(3) Best practice treatment for pregnant mothers and newborns with prescription pain medication dependencies and addictions.

(c) This SECTION expires December 31, 2013.

SECTION 10. [EFFECTIVE JULY 1, 2013] **(a) As used in this SECTION, "commission" refers to the health finance commission established by IC 2-5-23-3.**

(b) During the 2013 legislative interim, the commission shall study the use of methadone and opioids in treatment programs and clinic settings.

(c) Not later than September 1, 2013, the division of mental health and addiction shall provide the commission with the following information in writing:

(1) The number of patients served in Indiana opioid treatment programs certified under IC 12-23-18.

(2) The opioid treatment medications provided to patients, including the dosage.

(3) The drug testing protocol of Indiana opioid treatment programs.

(4) The number of opioid treatment program patients who have tested positive for other controlled substances during a drug test for a controlled substance provided under an opioid treatment program.

(5) The number of opioid treatment program patients who are subsequently determined to no longer need the assistance of the opioid treatment program and released from treatment.

(6) Any other information that is requested by the commission or determined by the division of mental health and addiction to be relevant to the study described in this SECTION.

(d) This SECTION expires December 31, 2013.

SECTION 11. **An emergency is declared for this act.**

(Reference is to Engrossed Senate Bill 246 as printed March 26, 2013.)

Conference Committee Report
on
Engrossed Senate Bill 246

Signed by:

Senator Grooms Chairperson	Representative Davisson
Senator Breaux	Representative Stemler
Senate Conferees	**House Conferees**