



March 26, 2013

**ENGROSSED
SENATE BILL No. 246**

DIGEST OF SB 246 (Updated March 25, 2013 12:10 pm - DI 104)

Citations Affected: IC 12-15; IC 25-22.5; IC 35-31.5; IC 35-48; noncode.

Synopsis: Controlled substances. 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
(Continued next page)

Effective: Upon passage; July 1, 2013.

**Grooms, Charbonneau,
Miller Patricia, Arnold J, Breaux,
Becker, Hume, Young R, Steele,
Skinner, Hershman, Randolph**

(HOUSE SPONSORS — DAVISSON, CLERE, STEMLER, BACON)

January 7, 2013, read first time and referred to Committee on Health and Provider Services.

February 14, 2013, amended, reported favorably — Do Pass.

February 21, 2013, read second time, amended, ordered engrossed.

February 22, 2013, engrossed.

February 25, 2013, read third time, passed. Yeas 50, nays 0.

HOUSE ACTION

March 4, 2013, read first time and referred to Committee on Public Health.

March 26, 2013, amended, reported — Do Pass.

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Digest Continued

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.

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March 26, 2013

First Regular Session 118th General Assembly (2013)

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 2012 Regular Session of the General Assembly.

ENGROSSED SENATE BILL No. 246

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

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

- 1 SECTION 1. IC 12-15-35-51, AS ADDED BY P.L.36-2009,
2 SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
3 UPON PASSAGE]: Sec. 51. (a) As used in this section, "advisory
4 committee" refers to the mental health Medicaid quality advisory
5 committee established by subsection (b).
6 (b) The mental health Medicaid quality advisory committee is
7 established. The advisory committee consists of the following
8 members:
9 (1) The director of the office or the director's designee, who shall
10 serve as chairperson of the advisory committee.
11 (2) The director of the division of mental health and addiction or
12 the director's designee.
13 (3) A representative of a statewide mental health advocacy
14 organization.
15 (4) A representative of a statewide mental health provider
16 organization.
17 (5) A representative from a managed care organization that

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1 participates in the state's Medicaid program.

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

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

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

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

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

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

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

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

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

32 (1) Peer reviewed medical literature.

33 (2) Observational studies.

34 (3) Health economic studies.

35 (4) Input from physicians and patients.

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

38 (h) The office shall report recommendations made by the advisory
39 committee to the drug utilization review board established by section
40 19 of this chapter.

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

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- 1 (1) The advisory committee's advice and recommendations made
- 2 under this section.
- 3 (2) The number of restrictions implemented under
- 4 IC 12-15-35.5-7(c) and the outcome of each restriction.
- 5 (3) The transition of individuals who are aged, blind, or disabled
- 6 to the risk based managed care program. This information shall
- 7 also be reported to the health finance commission established by
- 8 IC 2-5-23-3.
- 9 (4) Any decision by the office to change the health care delivery
- 10 system in which Medicaid is provided to recipients.
- 11 (j) Notwithstanding subsection (b), the initial members appointed
- 12 to the advisory committee under this section are appointed for the
- 13 following terms:
- 14 (1) Individuals appointed under subsection (b)(3) and (b)(4) are
- 15 appointed for a term of four (4) years.
- 16 (2) An individual appointed under subsection (b)(5) is appointed
- 17 for a term of three (3) years.
- 18 (3) An individual appointed under subsection (b)(6) is appointed
- 19 for a term of two (2) years.
- 20 (4) An individual appointed under subsection (b)(7) is appointed
- 21 for a term of one (1) year.
- 22 This subsection expires December 31, 2013.
- 23 SECTION 2. IC 25-22.5-2-7, AS AMENDED BY P.L.225-2007,
- 24 SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
- 25 JULY 1, 2013]: Sec. 7. (a) The board shall do the following:
- 26 (1) Adopt rules and forms necessary to implement this article that
- 27 concern, but are not limited to, the following areas:
- 28 (A) Qualification by education, residence, citizenship,
- 29 training, and character for admission to an examination for
- 30 licensure or by endorsement for licensure.
- 31 (B) The examination for licensure.
- 32 (C) The license or permit.
- 33 (D) Fees for examination, permit, licensure, and registration.
- 34 (E) Reinstatement of licenses and permits.
- 35 (F) Payment of costs in disciplinary proceedings conducted by
- 36 the board.
- 37 (2) Administer oaths in matters relating to the discharge of ~~its~~ **the**
- 38 **board's** official duties.
- 39 (3) Enforce this article and assign to the personnel of the agency
- 40 duties as may be necessary in the discharge of the board's duty.
- 41 (4) Maintain, through the agency, full and complete records of all
- 42 applicants for licensure or permit and of all licenses and permits

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- 1 issued.
- 2 (5) Make available, upon request, the complete schedule of
- 3 minimum requirements for licensure or permit.
- 4 (6) Issue, at the board's discretion, a temporary permit to an
- 5 applicant for the interim from the date of application until the
- 6 next regular meeting of the board.
- 7 (7) Issue an unlimited license, a limited license, or a temporary
- 8 medical permit, depending upon the qualifications of the
- 9 applicant, to any applicant who successfully fulfills all of the
- 10 requirements of this article.
- 11 (8) Adopt rules establishing standards for the competent practice
- 12 of medicine, osteopathic medicine, or any other form of practice
- 13 regulated by a limited license or permit issued under this article.
- 14 (9) Adopt rules regarding the appropriate prescribing of Schedule
- 15 III or Schedule IV controlled substances for the purpose of weight
- 16 reduction or to control obesity.
- 17 (10) Adopt rules establishing standards for office based
- 18 procedures that require moderate sedation, deep sedation, or
- 19 general anesthesia.
- 20 **(11) Adopt rules establishing standards and protocols for the**
- 21 **prescribing of controlled substances.**
- 22 (b) The board may adopt rules that establish:
- 23 (1) certification requirements for child death pathologists;
- 24 (2) an annual training program for child death pathologists under
- 25 IC 16-35-7-3(b)(2); and
- 26 (3) a process to certify a qualified child death pathologist.
- 27 SECTION 3. IC 25-22.5-13 IS ADDED TO THE INDIANA CODE
- 28 AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE
- 29 UPON PASSAGE]:
- 30 **Chapter 13. Controlled Substance Rules**
- 31 **Sec. 1. (a) Before November 1, 2013, the board shall adopt**
- 32 **emergency rules in the manner provided under IC 4-22-2-37.1 to**
- 33 **establish standards and procedures to do the following:**
- 34 **(1) Receive and review petitions from the attorney general**
- 35 **seeking board authorization to examine a physician's records**
- 36 **and controlled substances inventory and materials to**
- 37 **investigate the physician's controlled substances prescribing**
- 38 **practices.**
- 39 **(2) Authorize, where appropriate, the attorney general to**
- 40 **examine records, materials, and inventory relating to the**
- 41 **physician's controlled substance prescribing practices.**
- 42 **(3) Provide safeguards and protections for physicians against**

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1 unreasonable and oppressive examination authorizations and
2 actions taken to carry out the authorizations, including
3 limitations on interference with regular practice operations
4 and other appropriate due process provisions.

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

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

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

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

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

19 (2) before November 1, 2014, adopt rules under IC 4-22-2;
20 to establish standards and protocols for the prescribing of
21 controlled substances.

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

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

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

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

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

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

42 (c) "Owner", for purposes of IC 35-49, has the meaning set forth

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1 in IC 35-49-1-6.

2 SECTION 5. IC 35-48-3-1.5 IS ADDED TO THE INDIANA CODE
3 AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
4 1, 2013]: **Sec. 1.5. (a) This section is effective beginning January 1,
5 2014.**

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

- 11 (1) A person licensed by a board listed in IC 25-1-9.
- 12 (2) A dentist licensed under IC 25-14.
- 13 (3) A physician licensed under IC 25-22.5.
- 14 (4) An optometrist licensed under IC 25-24.
- 15 (5) A podiatrist licensed under IC 25-29.
- 16 (6) A community mental health center certified under
17 IC 12-21-2-3(5)(C).
- 18 (7) A private mental health institution or private psychiatric
19 hospital licensed under IC 12-25.
- 20 (8) A hospital or ambulatory outpatient surgical center
21 licensed under IC 16-21.
- 22 (9) A hospice licensed under IC 16-25.
- 23 (10) A home health agency licensed under IC 16-27-1.
- 24 (11) A health facility licensed under IC 16-28.
- 25 (12) A rural health clinic (as defined in 42 U.S.C. 1396d(l)(1)).
- 26 (13) A federally qualified health center (as defined in 42
27 U.S.C. 1396d(l)(2)(B)).
- 28 (14) A pharmacist or pharmacy licensed under IC 25-26.
- 29 (15) A community health center (as defined in IC 34-18-2-9).
- 30 (16) An affiliate, member, partner, or subsidiary of any
31 person described in subdivisions (6) through (15).
- 32 (17) A:
 - 33 (A) corporation;
 - 34 (B) partnership;
 - 35 (C) joint venture;
 - 36 (D) limited liability company; or
 - 37 (E) professional corporation;
- 38 or any other entity in which more than fifty percent (50%) of
39 the owners, shareholders, partners, or members are persons
40 listed in subdivisions (1) through (16).

41 SECTION 6. IC 35-48-3-3 IS AMENDED TO READ AS
42 FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 3. (a) Every person who**

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1 manufactures or distributes any controlled substance within this state
 2 or who proposes to engage in the manufacture or distribution of any
 3 controlled substance within this state, must obtain biennially a
 4 registration issued by the board in accordance with ~~its~~ **the board's**
 5 rules.

6 (b) Every person who dispenses or proposes to dispense any
 7 controlled substance within Indiana must have a registration issued by
 8 the board in accordance with ~~its~~ **the board's** rules. A registration
 9 issued to a dispenser under this subsection expires whenever the
 10 dispenser's license as a practitioner expires. The board shall renew a
 11 dispenser's registration under this subsection concurrently with any
 12 state license authorizing the dispenser to act as a practitioner.

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

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

25 ~~(d)~~ **(e)** The following persons need not register and may lawfully
 26 possess controlled substances under this article:

27 (1) An agent or employee of any registered manufacturer,
 28 distributor, or dispenser of any controlled substance if ~~he~~ **the**
 29 **agent or employee** is acting in the usual course of ~~his~~ **the agent's**
 30 **or employee's** business or employment.

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

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

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

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

42 (1) manufactures, distributes, dispenses, or possesses controlled

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1 substances; and
2 **(2) employs or contracts with individuals to dispense**
3 **controlled substances. This subdivision is effective January 1,**
4 **2014.**

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

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

- 11 **(1) issue an injunction;**
- 12 **(2) order the owner to pay a civil penalty not to exceed five**
13 **thousand dollars (\$5,000);**
- 14 **(3) order the owner to pay the state the reasonable costs of the**
15 **attorney general's investigation and prosecution related to the**
16 **action; and**
- 17 **(4) provide the appointment of a receiver.**

18 SECTION 7. [EFFECTIVE JULY 1, 2013] **(a) As used in this**
19 **SECTION, "commission" refers to the health finance commission**
20 **established by IC 2-5-23-3.**

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

28 **(c) This SECTION expires December 31, 2013.**

29 SECTION 8. [EFFECTIVE JULY 1, 2013] **(a) As used in this**
30 **SECTION, "commission" refers to the Indiana commission on**
31 **mental health and addiction established by IC 12-21-6.5-2.**

32 **(b) During the 2013 legislative interim, the commission shall**
33 **study issues concerning treatment and recovery from prescription**
34 **drug use addiction. The commission shall study and make**
35 **recommendations concerning the following:**

- 36 **(1) Use of the Indiana health care professional recruitment**
37 **and retention fund established by IC 16-46-5-8 to provide loan**
38 **repayment for student loans incurred by addiction**
39 **professionals.**
- 40 **(2) Criteria for Medicaid reimbursement for detoxification**
41 **and rehabilitation services for addiction treatment.**
- 42 **(3) Best practice treatment for pregnant mothers and**

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1 newborns with prescription pain medication dependencies
 2 and addictions.
 3 (c) This SECTION expires December 31, 2013.
 4 SECTION 9. [EFFECTIVE JULY 1, 2013] (a) As used in this
 5 SECTION, "commission" refers to the health finance commission
 6 established by IC 2-5-23-3.
 7 (b) During the 2013 legislative interim, the commission shall
 8 study the use of methadone and opioids in treatment programs and
 9 clinic settings.
 10 (c) Not later than September 1, 2013, the division of mental
 11 health and addiction shall provide the commission with the
 12 following information in writing:
 13 (1) The number of patients served in Indiana opioid treatment
 14 programs certified under IC 12-23-18.
 15 (2) The opioid treatment medications provided to patients,
 16 including the dosage.
 17 (3) The drug testing protocol of Indiana opioid treatment
 18 programs.
 19 (4) The number of opioid treatment program patients who
 20 have tested positive for other controlled substances during a
 21 drug test for a controlled substance provided under an opioid
 22 treatment program.
 23 (5) The number of opioid treatment program patients who are
 24 subsequently determined to no longer need the assistance of
 25 the opioid treatment program and released from treatment.
 26 (6) Any other information that is requested by the commission
 27 or determined by the division of mental health and addiction
 28 to be relevant to the study described in this SECTION.
 29 (d) This SECTION expires December 31, 2013.
 30 SECTION 10. An emergency is declared for this act.

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COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 246, 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:

Delete the title and insert the following:

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

Replace the effective date in SECTION 1 with "[EFFECTIVE UPON PASSAGE]".

Page 1, line 4, delete "CLINICS" and insert "**PRESCRIBING OVERSIGHT**".

Page 1, line 5, after "Definitions" insert "; **Investigations and Compliance**".

Page 1, line 6, delete "(a)".

Page 1, line 6, delete ""controlled drug clinic" means" and insert "**person" means an individual, a corporation, a partnership, a joint venture, or any other entity.**".

Page 1, delete lines 7 through 17.

Page 2, delete lines 1 through 17.

Page 2, line 18, delete "A controlled drug clinic shall not operate in Indiana" and insert "**Except as provided in subsection (b), this chapter applies to any person that:**

(1) prescribes, dispenses, or administers controlled substances to human patients; and

(2) either:

(A) is required to obtain a controlled substances registration under IC 35-48-3-3; or

(B) supervises, employs, or manages another person who is required to obtain a controlled substances registration under IC 35-48-3-3.

(b) This chapter does not apply to the following:

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

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

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

Sec. 3. (a) This section is effective January 1, 2014.

(b) After December 31, 2013, a person may not have an ownership interest in an entity that is described in section 2(a) of this chapter unless the person is:

(1) a physician or osteopathic physician licensed under IC 25-22.5;

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- (2) a hospital licensed under IC 16-21; or
- (3) a health facility licensed under IC 16-28.

Sec. 4. The medical licensing board or the board's authorized representative may conduct an annual onsite visit of each entity described in section 2(a) of this chapter to determine whether the entity is complying with this chapter.

Sec. 5. (a) Subject to the provisions of this chapter, the medical licensing board may authorize the attorney general to inspect the premises and records of an entity described in section 2(a) of this chapter to assess compliance with this chapter."

Page 2, delete lines 19 through 42.

Page 3, delete lines 1 through 25.

Page 3, line 26, delete "(d)" and insert "**(b)**".

Page 3, line 28, delete "(c)." and insert "**(a)**".

Page 3, line 29, delete "(e)" and insert "**Sec. 6.**".

Page 3, line 32, delete ":" and insert "**that a person has violated or is in imminent danger of violating provisions of this chapter or any other statute or rule concerning the prescribing, dispensing, or administering of a controlled substance by an entity described in section 2(a) of this chapter.**".

Page 3, delete lines 33 through 41.

Page 3, line 42, delete "(f)" and insert "**Sec. 7.**".

Page 4, line 1, delete "subsection (e)," and insert "**section 6 of this chapter,**".

Page 4, line 4, delete "controlled" and insert "**health care provider**".

Page 4, line 5, delete "drug clinic, a physician, or a practitioner".

Page 4, line 8, delete "controlled drug clinic".

Page 4, line 9, delete "or".

Page 4, line 9, after "facility" insert ", **clinic, office, or location**".

Page 4, delete lines 24 through 42, begin a new paragraph and insert:

"Sec. 8. A petition for judicial review under IC 4-21.5-5 may not be filed before:

- (1) all other available administrative remedies have been exhausted; and**
- (2) a board, commission, or agency has taken final action and the final action is the subject of review.**

Sec. 9. Nothing in this article prohibits the attorney general from taking action before the effective date of rules promulgated as required under IC 25-11.5-2.

Chapter 2. Rules



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Sec. 1. (a) Consistent with standard medical practices in pain management treatment, the medical licensing board shall, before October 1, 2013, adopt rules under IC 4-22-2 to establish and administer a controlled drug prescribing oversight program for persons described in IC 25-11.5-1-2.

(b) The rules required under subsection (a) must establish the appropriate standards for operation of a facility, clinic, office, or location where controlled substances are prescribed, dispensed, or administered to human patients.

(c) The rules required under subsection (a) must include provisions addressing the following:

(1) Minimum requirements for a licensed physician's initial evaluation of each patient, including any appropriate use of the INSPECT program data base.

(2) Minimum requirements for a licensed physician's regular physical evaluation, progress evaluation, and individualized medical treatment plan for each patient.

(3) Minimum staffing and oversight requirements by licensed and unlicensed personnel, including any appropriate staffing ratios and any appropriate physical presence requirements.

(4) Clinical standards for alternative treatment methods.

(5) Appropriate continuing medical education requirements.

(6) All other factors that the board determines are relevant to safe and effective controlled substances prescribing, dispensing, and administration practices.

Sec. 2. 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 as part of the controlled drug prescribing oversight program under section 1 of this chapter.

Sec. 3. 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. 4. 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.

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SECTION 2. An emergency is declared for this act."

Delete pages 5 through 7.

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 246 as introduced.)

MILLER PATRICIA, Chairperson

Committee Vote: Yeas 10, Nays 0.

SENATE MOTION

Madam President: I move that Senate Bill 246 be amended to read as follows:

Page 2, between lines 5 and 6, begin a new line block indented and insert:

"(4) A pharmacy holding a permit issued under IC 25-26-13.

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

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

Page 2, line 13, delete "a health facility licensed under IC 16-28." and insert "**a hospice licensed under IC 16-25.**"

Page 2, delete lines 14 through 42, begin a new line blocked left and insert:

"A physician licensed under IC 25-22.5 must hold a majority interest in the entity and the remaining interest must be held by a health care provider licensed in Indiana.

SECTION 2. IC 25-22.5-13 IS ADDED TO THE INDIANA CODE AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]:

Chapter 13. Controlled Substance Rules

Sec. 1. (a) Before October 31, 2013, the board shall adopt emergency rules in the manner provided under IC 4-22-2-37.1 related to the prescribing of controlled substances to establish a process for the office of the attorney general to follow to access a physician's records and inventory.

(b) The rules adopted under this section may not affect any other process the attorney general is authorized to follow in obtaining records for an investigation."

Page 3, delete lines 1 through 23.

Page 3, line 24, delete "1." and insert "2."

Page 3, line 26, delete "and" and insert "**standards and protocols**

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for the prescribing of controlled substances."

Page 3, delete lines 27 through 42.

Page 4, delete lines 1 through 6.

Page 4, line 7, delete "2." and insert "3."

Page 4, line 11, delete "as part of the controlled drug prescribing oversight".

Page 4, line 12, delete "program".

Page 4, line 12, delete "section 1 of".

Page 4, line 13, delete "3." and insert "4."

Page 4, line 16, delete "4." and insert "5."

Renumber all SECTIONS consecutively.

(Reference is to SB 246 as printed February 15, 2013.)

GROOMS

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred Senate Bill 246, 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 1, delete lines 1 through 17, begin a new paragraph and insert:

"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.

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(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

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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 P.L.225-2007, SECTION 3, 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.

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(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 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."

Page 2, delete lines 1 through 19.

Page 2, line 22, delete "JULY 1, 2013]" and insert "UPON PASSAGE]:".

Page 2, line 24, delete "October 31, 2013," and insert "**November 1, 2013,**".

Page 2, line 25, after "IC 4-22-2-37.1" insert "**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

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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."

Page 2, delete lines 26 through 31.

Page 2, line 33, delete "shall, before" and insert "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)."

Page 2, delete lines 34 through 35.

Page 3, between lines 4 and 5, begin a new paragraph and insert:

"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:

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- (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



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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:**

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- (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. [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 8. [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 9. [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

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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."

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 246 as reprinted February 22, 2013.)

CLERE, Chair

Committee Vote: yeas 9, nays 0.

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