



February 15, 2013

SENATE BILL No. 246

DIGEST OF SB 246 (Updated February 14, 2013 9:26 am - DI 104)

Citations Affected: IC 25-11.5.

Synopsis: Controlled drug prescribing oversight. Authorizes the medical licensing board (board) or the board's representative to conduct annual onsite visits of described persons that prescribe, dispense, or administer controlled substances to human patients. Allows the attorney general to petition the board in good faith for an inspection, and allows the board to authorize the attorney general to inspect and inventory premises and records of described persons. Specifies circumstances for the filing of a petition for judicial review. Requires the board, before October 1, 2013, to adopt rules to establish and administer a controlled drug prescribing oversight program, and include in the rules standards for operating a facility where controlled substances are prescribed, dispensed, or administered to human patients. Requires the state board of pharmacy and other boards that oversee controlled substance registrations to adopt necessary rules to complement rules adopted by the board as part of the controlled drug prescribing oversight program.

Effective: Upon passage.

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

January 7, 2013, read first time and referred to Committee on Health and Provider Services.
February 14, 2013, amended, reported favorably — Do Pass.

SB 246—LS 6619/DI 104+



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February 15, 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.

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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 25-11.5 IS ADDED TO THE INDIANA CODE AS
2 A NEW ARTICLE TO READ AS FOLLOWS [EFFECTIVE UPON
3 PASSAGE]:
4 **ARTICLE 11.5. CONTROLLED DRUG PRESCRIBING**
5 **OVERSIGHT**
6 **Chapter 1. Definitions; Investigations and Compliance**
7 **Sec. 1. As used in this article, "person" means an individual, a**
8 **corporation, a partnership, a joint venture, or any other entity.**
9 **Sec. 2. (a) Except as provided in subsection (b), this chapter**
10 **applies to any person that:**
11 **(1) prescribes, dispenses, or administers controlled substances**
12 **to human patients; and**
13 **(2) either:**
14 **(A) is required to obtain a controlled substances**
15 **registration under IC 35-48-3-3; or**
16 **(B) supervises, employs, or manages another person who**
17 **is required to obtain a controlled substances registration**

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- 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;
- (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.

(b) The medical licensing board may designate a member for purposes of issuing the authorization of the attorney general specified in subsection (a).

Sec. 6. The attorney general may petition the medical licensing board or designated member of the medical licensing board for a compliance inspection authorization if the attorney general has a good faith reason to believe 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.

Sec. 7. Upon review of the attorney general's petition under section 6 of this chapter, the medical licensing board or its designated member may authorize the attorney general to immediately do the following:

- (1) Inspect and copy records maintained by the health care provider concerning the prescribing, dispensing, or administering of a controlled substance.
- (2) Inspect, in a reasonable manner, the facility, clinic, office, or location and:
 - (A) any equipment;

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- 1 (B) any material;
- 2 (C) any containers;
- 3 (D) any labeling;
- 4 (E) any records;
- 5 (F) any files;
- 6 (G) any paper and electronic documents;
- 7 (H) any procedures;
- 8 (I) any controls; and
- 9 (J) anything relevant concerning compliance with this
- 10 chapter;

11 located on the premises.

- 12 (3) Inventory controlled substances on the premises, and
- 13 obtain samples of the controlled substances.

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

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

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

23 Chapter 2. Rules

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

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

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

- 35 (1) Minimum requirements for a licensed physician's initial
- 36 evaluation of each patient, including any appropriate use of
- 37 the INSPECT program data base.
- 38 (2) Minimum requirements for a licensed physician's regular
- 39 physical evaluation, progress evaluation, and individualized
- 40 medical treatment plan for each patient.
- 41 (3) Minimum staffing and oversight requirements by licensed
- 42 and unlicensed personnel, including any appropriate staffing

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1 ratios and any appropriate physical presence requirements.
 2 (4) Clinical standards for alternative treatment methods.
 3 (5) Appropriate continuing medical education requirements.
 4 (6) All other factors that the board determines are relevant to
 5 safe and effective controlled substances prescribing,
 6 dispensing, and administration practices.
 7 Sec. 2. The state board of pharmacy or any licensing board,
 8 commission, or agency that controls, authorizes, or oversees
 9 controlled substance registrations under IC 35-48-3 shall adopt
 10 rules necessary to complement the rules adopted by the medical
 11 licensing board as part of the controlled drug prescribing oversight
 12 program under section 1 of this chapter.
 13 Sec. 3. A board, commission, or agency required to adopt rules
 14 under this chapter may adopt emergency rules in the manner
 15 provided under IC 4-22-2-37.1 for the same purposes.
 16 Sec. 4. For purposes of Executive Order 13-03, the predominate
 17 purpose and effect of rules adopted under this chapter is to address
 18 emergency matters of health and safety.
 19 SECTION 2. 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.

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