



Reprinted
February 22, 2013

SENATE BILL No. 246

DIGEST OF SB 246 (Updated February 21, 2013 2:00 pm - DI 107)

Citations Affected: IC 25-11.5; IC 25-22.5.

Synopsis: Controlled substances. Allows only specified persons to have an ownership interest in an entity that prescribes, dispenses, or administers controlled substances. Requires the board, before October 1, 2013, to adopt rules to establish standards and protocols for the prescribing of controlled substances. 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 concerning standards and protocols for the prescribing of controlled substances.

Effective: Upon passage; July 1, 2013.

**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.

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

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SB 246—LS 6619/DI 104+



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.

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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1 under IC 35-48-3-3.

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

- 3 (1) A dentist licensed under IC 25-14.
 4 (2) A podiatrist licensed under IC 25-29.
 5 (3) A pharmacist licensed under IC 25-26.
 6 (4) A pharmacy holding a permit issued under IC 25-26-13.
 7 (5) An optometrist licensed under IC 25-24.
 8 (6) A health facility licensed under IC 16-28.

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

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

- 13 (1) a physician or osteopathic physician licensed under
 14 IC 25-22.5;
 15 (2) a hospital licensed under IC 16-21; or
 16 (3) a hospice licensed under IC 16-25.

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

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

23 **Chapter 13. Controlled Substance Rules**

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

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

32 Sec. 2. (a) Consistent with standard medical practices in pain
 33 management treatment, the medical licensing board shall, before
 34 October 1, 2013, adopt rules under IC 4-22-2 to establish standards
 35 and protocols for the prescribing of controlled substances.

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

41 Sec. 4. A board, commission, or agency required to adopt rules
 42 under this chapter may adopt emergency rules in the manner

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1 provided under IC 4-22-2-37.1 for the same purposes.
2 **Sec. 5. For purposes of Executive Order 13-03, the predominate**
3 **purpose and effect of rules adopted under this chapter is to address**
4 **emergency matters of health and safety.**
5 **SECTION 3. 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.)

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