

SENATE BILL No. 246

DIGEST OF INTRODUCED BILL

Citations Affected: IC 25-11.5.

Synopsis: Certification of controlled drug clinics. Requires a controlled drug clinic to be certified by the medical licensing board. Sets forth requirements for controlled drug clinics.

Effective: July 1, 2013.

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

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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 and to make an appropriation.

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 JULY 1,
 3 2013]:
 4 **ARTICLE 11.5. CONTROLLED DRUG CLINICS**
 5 **Chapter 1. Definitions**
 6 **Sec. 1. (a) As used in this article, "controlled drug clinic" means**
 7 **a facility that meets all the following:**
 8 **(1) The facility provides treatment for pain that includes the**
 9 **prescribing, dispensing, or administering of controlled**
 10 **substances by any of the following:**
 11 **(A) A physician who is:**
 12 **(i) licensed under IC 25-22.5; and**
 13 **(ii) employed by, or acting on behalf of, the clinic.**
 14 **(B) A practitioner who is:**
 15 **(i) licensed or certified in Indiana to prescribe, dispense,**
 16 **or administer a controlled substance; and**
 17 **(ii) employed by, or acting on behalf of, the clinic.**



1 (2) The majority of the patients of the physicians and
 2 practitioners at the facility are provided treatment for pain
 3 that includes the use of controlled substances.

4 (3) Either:

5 (A) the facility's primary practice component is the
 6 treatment of pain; or

7 (B) the facility advertises in a medium soliciting or offering
 8 any type of pain management services.

9 (b) The term does not include the following:

10 (1) A hospital:

11 (A) licensed under IC 16-21-2; or

12 (B) subject to IC 16-22 or IC 16-23.

13 (2) An ambulatory outpatient surgical center licensed under
 14 IC 16-21-2.

15 (3) A hospice program licensed under IC 16-25-3.

16 (4) A health facility licensed under IC 16-28-2.

17 (5) A facility operated by the state or federal government.

18 Sec. 2. (a) A controlled drug clinic shall not operate in Indiana
 19 unless:

20 (1) the pain management treatment program is:

21 (A) specifically approved by; and

22 (B) in compliance with;

23 state and federal law; and

24 (2) the controlled drug clinic is:

25 (A) owned and operated by a physician licensed under
 26 IC 25-22.5; and

27 (B) certified by the medical licensing board.

28 (b) Separate specific approval and certification under this
 29 chapter is required for each location of a controlled drug clinic in
 30 which a pain management treatment program is operated.

31 Sec. 3. In order to obtain certification and maintain certification
 32 under this chapter, the controlled drug clinic must meet the
 33 following requirements:

34 (1) Be owned by a physician licensed under IC 25-22.5.

35 (2) Provide each patient of the clinic with an individualized
 36 medical plan that treats the patient and avoids long term pain
 37 medication addiction.

38 (3) Have a physician licensed under IC 25-22.5 physically
 39 present at the clinic at all times that the controlled drug clinic
 40 is open.

41 (4) Before a controlled substance is prescribed for a patient,
 42 use the INSPECT program established by IC 25-1-13-4.

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1 **Sec. 4. (a) Consistent with standard medical practices in pain**
 2 **management treatment, the medical licensing board shall adopt**
 3 **rules under IC 4-22-2 to establish and administer a controlled drug**
 4 **clinic oversight program. The rules must address the following:**

5 **(1) Standards for operation of a controlled drug clinic,**
 6 **including the following:**

7 **(A) Minimum requirements for a licensed physician's**
 8 **regular physical evaluation and progress evaluation of**
 9 **each clinic patient.**

10 **(B) Minimum staffing requirements by licensed and**
 11 **unlicensed personnel.**

12 **(C) Clinical standards for the appropriate tapering of a**
 13 **patient off of controlled substance medication.**

14 **(2) Fees to be paid by a controlled drug clinic for deposit in**
 15 **the controlled drug clinic regulation fund established by**
 16 **section 6 of this chapter for annual certification under this**
 17 **chapter. The fees must be sufficient to pay the cost of**
 18 **implementing this chapter.**

19 **(b) The medical licensing board may conduct an annual onsite**
 20 **visit of each controlled drug clinic to assess compliance with the**
 21 **provisions of this chapter.**

22 **(c) Subject to the provisions of this section, the medical licensing**
 23 **board may authorize the attorney general to inspect the premises**
 24 **and records of a controlled drug clinic to assess compliance with**
 25 **this chapter.**

26 **(d) The medical licensing board may designate a member for**
 27 **purposes of issuing the authorization of the attorney general**
 28 **specified in subsection (c).**

29 **(e) The attorney general may petition the medical licensing**
 30 **board or designated member of the medical licensing board for a**
 31 **compliance inspection authorization if the attorney general has a**
 32 **good faith reason to believe:**

33 **(1) that a controlled drug clinic has violated or is in imminent**
 34 **danger of violating provisions of this chapter or any other**
 35 **statute or regulation concerning the prescribing, dispensing,**
 36 **or administering of a controlled substance by a physician or**
 37 **practitioner specified in section 1 of this chapter; or**

38 **(2) that a person is operating as a controlled drug clinic:**

39 **(A) without possessing the certification required by this**
 40 **chapter; or**

41 **(B) in violation of this chapter.**

42 **(f) Upon review of the attorney general's petition under**

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1 subsection (e), the medical licensing board or its designated
 2 member may authorize the attorney general to immediately do the
 3 following:

4 (1) Inspect and copy records maintained by the controlled
 5 drug clinic, a physician, or a practitioner concerning the
 6 prescribing, dispensing, or administering of a controlled
 7 substance.

8 (2) Inspect, in a reasonable manner, the controlled drug clinic
 9 or facility and:

10 (A) any equipment;

11 (B) any material;

12 (C) any containers;

13 (D) any labeling;

14 (E) any records;

15 (F) any files;

16 (G) any paper and electronic documents;

17 (H) any procedures;

18 (I) any controls; and

19 (J) anything relevant concerning compliance with this
 20 chapter;

21 located on the premises.

22 (3) Inventory controlled substances on the premises, and
 23 obtain samples of the controlled substances.

24 Sec. 5. (a) The medical licensing board may take any of the
 25 following actions based on any grounds described in subsection (b):

26 (1) Issue a letter of correction.

27 (2) Order the inspection or reinspection of a controlled drug
 28 clinic.

29 (3) Deny renewal of, or revoke certification of, a controlled
 30 drug clinic.

31 (4) Impose a civil penalty in an amount not to exceed ten
 32 thousand dollars (\$10,000).

33 (b) The medical licensing board may take action under
 34 subsection (a) based on any of the following grounds:

35 (1) Violation of this chapter or rules adopted under this
 36 chapter.

37 (2) Permitting, aiding, or abetting in the commission of any
 38 illegal act in a controlled drug clinic.

39 (3) Conduct or practice found by the medical licensing board
 40 to be detrimental to the welfare of a controlled drug clinic
 41 patient.

42 (c) IC 4-21.5 applies to an action under this section.

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1 **Sec. 6. (a) The controlled drug clinic regulation fund is**
 2 **established for the purpose of administering this chapter. The fund**
 3 **shall be administered by the professional licensing agency on**
 4 **behalf of the medical licensing board.**

5 **(b) The expenses of administering the fund shall be paid from**
 6 **money in the fund.**

7 **(c) The treasurer of state shall invest money in the fund in the**
 8 **same manner as other public money may be invested.**

9 **(d) Money in the fund at the end of the state fiscal year does not**
 10 **revert to the state general fund.**

11 **(e) Money in the fund is continually appropriated.**

12 **Sec. 7. The medical licensing board may consider the following**
 13 **factors in determining whether a facility meets the definition of a**
 14 **controlled drug clinic:**

15 **(1) The physician or practitioner does not perform a physical**
 16 **examination of the patient or performs a cursory physical**
 17 **examination of the patient.**

18 **(2) The facility creates or maintains incomplete, cursory, or**
 19 **no patient histories.**

20 **(3) The facility does not require or request a patient's medical**
 21 **records.**

22 **(4) The facility's medical equipment and exam rooms fall**
 23 **below the standard of practice for the industry.**

24 **(5) The facility has a single source referral for laboratory,**
 25 **imaging, or pharmacy services.**

26 **(6) The facility does not create or maintain treatment plans or**
 27 **engage in clinical monitoring of a patient.**

28 **(7) The facility has multiple patients with the same last name**
 29 **receiving controlled substances.**

30 **(8) The facility:**

31 **(A) fails to use;**

32 **(B) is inconsistent in the facility's use of; or**

33 **(C) disregards the results of;**

34 **a urine drug screen for a patient.**

35 **(9) The facility makes few or no referrals to health care**
 36 **specialists.**

37 **(10) The facility does no or does minimal diagnostic testing.**

38 **(11) The facility's sole or primary emphasis is controlled**
 39 **substance treatment.**

40 **(12) The facility dispenses controlled substances.**

41 **(13) The facility frequently prescribes, dispenses, or permits**
 42 **early refills of controlled substances.**

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- 1 (14) The facility employs a security guard during normal
2 business hours.
- 3 (15) The facility accepts only cash payments for office visits.
- 4 (16) The facility accepts only cash payments for procedures
5 and does not accept health insurance.
- 6 (17) The facility regularly has long lines of patients waiting
7 for treatment or prescriptions.
- 8 (18) The facility is not owned by a physician or practitioner.
- 9 (19) The facility is a franchise or part of a multistate business
10 operation.
- 11 (20) The physician or practitioner knowingly treats a drug
12 addict without legal authorization.
- 13 (21) The physician or practitioner disregards clinical
14 comorbidities.
- 15 (22) The physician or practitioner disregards a patient's
16 history of drug abuse, diversion, or addiction.
- 17 (23) A patient of the facility:
18 (A) overdosed on a controlled substance; or
19 (B) died because of a controlled substance;
20 prescribed by the facility.
- 21 (24) A patient has been admitted to the hospital emergency
22 department because of a pharmacy complication resulting, at
23 least in part, from a controlled substance prescribed by the
24 facility.
- 25 (25) The physician or practitioner prescribes a controlled
26 substance to a patient who is obtaining, according to records
27 maintained in the INSPECT program data base, the same or
28 a similar controlled substance from another provider during
29 the same period.
- 30 (26) The physician or practitioner continues to prescribe a
31 controlled substance for a patient when the patient's condition
32 is not improving.
- 33 (27) The physician or practitioner prescribes similar
34 controlled substance combinations for multiple patients.
- 35 (28) The physician or practitioner offers a controlled
36 substance for an unsubstantiated or vague diagnosis.
- 37 (29) The physician or practitioner prescribes concurrently
38 any combination of the following drugs:
39 (A) Benzodiazepines.
40 (B) Opiates.
41 (C) Muscle relaxers.
- 42 (30) The physician or practitioner prescribes concurrently a

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- 1 **controlled substance and a schedule III, IV, or V drug without**
- 2 **a corresponding diagnosis.**
- 3 **(31) The physician or practitioner prescribes concurrently**
- 4 **methadone and benzodiazepines.**
- 5 **(32) The physician or practitioner prescribes concurrently**
- 6 **two (2) or more long-acting opiates.**
- 7 **(33) The physician or practitioner prescribes a controlled**
- 8 **substance against indications.**
- 9 **(34) More than twenty percent (20%) of the facility's patients**
- 10 **are not residents of Indiana.**
- 11 **(35) A large number of the facility's patients were referred by**
- 12 **friends or family of existing or former patients.**
- 13 **(36) One (1) or more of the physicians or practitioners at the**
- 14 **facility are not board certified in pain management.**

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