
SENATE BILL No. 157

DIGEST OF INTRODUCED BILL

Citations Affected: IC 12-7-2-135.6; IC 12-23; IC 16-18-2-264.3; IC 16-25.5.

Synopsis: Opioid treatment programs. Changes the term "methadone treatment" to "opioid treatment" for purposes of the law concerning certification of opiate addiction treatment programs. Requires certification standards and certification and licensure related to opioid treatment programs. Requires the establishment of certain fees and amends other fees. Specifies violations and penalties. Repeals the expiration of current law requiring a methadone diversion control and oversight program. (The introduced version of this bill was prepared by the health finance commission.)

Effective: July 1, 2008.

Miller

January 8, 2008, read first time and referred to Committee on Health and Provider Services.

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Second Regular Session 115th General Assembly (2008)

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 2007 Regular Session of the General Assembly.

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SENATE BILL No. 157



A BILL FOR AN ACT to amend the Indiana Code concerning health.

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

1 SECTION 1. IC 12-7-2-135.6 IS ADDED TO THE INDIANA
2 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
3 [EFFECTIVE JULY 1, 2008]: **Sec. 135.6. "Opioid treatment**
4 **program" means a program through which opioid agonist**
5 **medication is dispensed to an individual in the treatment of opiate**
6 **addiction and for which certification is required under 42 C.F.R.**
7 **8.**

8 SECTION 2. IC 12-23-1-10 IS AMENDED TO READ AS
9 FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 10. (a) The division is
10 the state authority primarily responsible for prevention, control,
11 treatment and rehabilitation, education, research, and planning in the
12 field of addictions. All other agencies of state and local government
13 shall cooperate with the division to assist in the performance of the
14 division's functions.

15 (b) **The division shall cooperate with the state department of**
16 **health in the performance of the state department's functions**
17 **under IC 16-25.5.**



1 SECTION 3. IC 12-23-18-0.5 IS ADDED TO THE INDIANA
2 CODE AS A NEW SECTION TO READ AS FOLLOWS
3 [EFFECTIVE JULY 1, 2008]: **Sec. 0.5. (a) An opioid treatment
4 program shall not operate in Indiana unless:**

- 5 (1) the opioid treatment program is certified by the division;
- 6 (2) after June 30, 2009, the facility in which the opioid
7 treatment program is operated is licensed under IC 16-25.5;
- 8 and
- 9 (3) the opioid treatment program is in compliance with state
10 and federal law.

11 (b) Separate certification under this chapter is required for each
12 location at which an opioid treatment program is operated.

13 SECTION 4. IC 12-23-18-1 IS AMENDED TO READ AS
14 FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 1. (a) Subject to federal
15 law and consistent with standard medical practice in ~~methadone~~ **opioid**
16 treatment of drug abuse, the division shall adopt rules under IC 4-22-2
17 to establish and administer a ~~methadone~~ **an opioid treatment** diversion
18 control and oversight program to identify individuals who divert
19 ~~controlled substances~~ **opioid treatment medications** from legitimate
20 treatment use and to terminate the ~~methadone~~ **opioid** treatment of those
21 individuals.

22 (b) Rules adopted under subsection (a) must include provisions
23 relating to the following matters concerning ~~methadone providers~~
24 **opioid treatment programs** and ~~individuals~~ **patients** who receive
25 **opioid** treatment:

- 26 (1) Regular clinic attendance by the patient.
- 27 (2) Specific counseling requirements for the ~~methadone provider~~
28 **opioid treatment program**.
- 29 (3) Serious behavior problems of the patient.
- 30 (4) Stable home environment of the patient.
- 31 (5) Safe storage capacity of **opioid** treatment medications within
32 the patient's home.
- 33 (6) Medically recognized testing protocols to determine legitimate
34 **opioid** treatment **medication** use.
- 35 (7) The ~~methadone provider's~~ **opioid treatment program's**
36 medical director and administrative staff responsibilities for
37 preparing and implementing a diversion control plan.

38 SECTION 5. IC 12-23-18-2 IS AMENDED TO READ AS
39 FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 2. (a) Not later than
40 February 28 of each year, each ~~methadone provider~~ **opioid treatment**
41 **program** must submit to the division a diversion control plan ~~required~~
42 **under that meets the requirements of section ~~1(b)(7)~~ 1** of this

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chapter.

(b) Not later than May 1 of each year, the division shall review and approve ~~plans a plan~~ submitted under subsection (a).

(c) If the division denies a plan submitted under subsection (a), the ~~methadone provider opioid treatment program~~ must submit another plan not later than sixty (60) days after the denial of the plan.

SECTION 6. IC 12-23-18-3 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 3. (a) By May 15 of each year, each ~~methadone provider opioid treatment program~~ shall submit to the division a fee of:

(1) twenty dollars (\$20) for each **resident; and**

(2) **three hundred dollars (\$300) for each nonresident; patient of Indiana who was treated by the methadone provider opioid treatment program** during the preceding ~~calendar~~ **calendar** year.

(b) The fee collected under subsection (a) shall be deposited in the ~~methadone diversion control and oversight program fund. established under section 4 of this chapter.~~

SECTION 7. IC 12-23-18-4 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 4. (a) As used in this section, "fund" means the ~~methadone opioid treatment diversion control and oversight program fund established under subsection (b).~~

(b) The ~~methadone opioid treatment diversion control and oversight program fund is established to administer and carry out the purposes of implement~~ this chapter. The fund shall be administered by the division.

(c) The expenses of administering the fund shall be paid from money in the fund.

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

(e) Money in the fund at the end of the state fiscal year does not revert to the state general fund.

SECTION 8. IC 12-23-18-5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 5. (a) **The division shall adopt rules under IC 4-22-2 to establish the following:**

(1) Standards for operation of an opioid treatment program in Indiana, including the following requirements:

(A) An opioid treatment program shall obtain prior authorization from the division for any patient receiving more than fourteen (14) days of opioid treatment medications at one (1) time.

(B) Minimum requirements for a licensed physician's regular:

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1 (i) physical presence in the opioid treatment facility; and
 2 (ii) physical evaluation and progress evaluation of each
 3 opioid treatment program patient.
 4 (C) Minimum staffing requirements by licensed and
 5 unlicensed personnel.
 6 (2) Fees to be paid by an opioid treatment program for
 7 deposit in the fund for annual certification under this chapter.
 8 The fees established under this subsection must be sufficient to pay
 9 the cost of implementing this chapter.
 10 (b) The division shall conduct an annual onsite visit of each
 11 methadone provider opioid treatment program facility to assess
 12 compliance with the plan approved under this chapter.
 13 SECTION 9. IC 12-23-18-5.5, AS ADDED BY P.L.210-2007,
 14 SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 15 JULY 1, 2008]: Sec. 5.5. (a) The division may not grant specific
 16 approval to be a new opioid treatment program. This section does not
 17 apply to applications for new opioid treatment programs pending prior
 18 to March 1, 2007.
 19 (b) This section expires December 31, 2008.
 20 SECTION 10. IC 12-23-18-5.6 IS ADDED TO THE INDIANA
 21 CODE AS A NEW SECTION TO READ AS FOLLOWS
 22 [EFFECTIVE JULY 1, 2008]: Sec. 5.6. (a) The division shall
 23 establish a central registry to maintain information concerning
 24 each patient served by an opioid treatment program.
 25 (b) An opioid treatment program shall, at least monthly, provide
 26 to the division information required by the division concerning
 27 patients currently served by the opioid treatment program.
 28 (c) Information that could be used to identify an opioid
 29 treatment program patient and that is:
 30 (1) contained in; or
 31 (2) provided to the division and related to;
 32 the central registry is confidential.
 33 SECTION 11. IC 12-23-18-5.7 IS ADDED TO THE INDIANA
 34 CODE AS A NEW SECTION TO READ AS FOLLOWS
 35 [EFFECTIVE JULY 1, 2008]: Sec. 5.7. (a) The division shall, as part
 36 of the biennial report required under IC 12-21-5-1.5(8), prepare
 37 and submit to the legislative council in an electronic format under
 38 IC 5-14-6 and to the governor a report concerning treatment
 39 offered by opioid treatment programs. The report must contain the
 40 following information for each of the two (2) previous calendar
 41 years:
 42 (1) The number of opioid treatment programs in Indiana.

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- 1 (2) The number of patients receiving opioid treatment in
- 2 Indiana.
- 3 (3) The length of time each patient received opioid treatment
- 4 and the average length of time all patients received opioid
- 5 treatment.
- 6 (4) The cost of each patient's opioid treatment and the
- 7 average cost of opioid treatment.
- 8 (5) The rehabilitation rate of patients who received opioid
- 9 treatment.
- 10 (6) The number of patients who became addicted to opioid
- 11 treatment medication.
- 12 (7) The number of patients who were rehabilitated and are no
- 13 longer receiving opioid treatment.
- 14 (8) The number of individuals, by geographic area, who are
- 15 on a waiting list to receive opioid treatment.
- 16 (9) The patient information reported to the central registry
- 17 established under section 5.6 of this chapter.
- 18 (b) Each opioid treatment program in Indiana shall provide
- 19 information requested by the division for the report required by
- 20 this section.
- 21 (c) Failure of an opioid treatment program to submit the
- 22 information required under subsection (a) may result in suspension
- 23 or termination of the opioid treatment program's certification.
- 24 (d) Information that could be used to identify an opioid
- 25 treatment program patient and that is:
- 26 (1) contained in; or
- 27 (2) provided to the division related to;
- 28 the report required by this section is confidential.
- 29 SECTION 12. IC 16-18-2-264.3 IS ADDED TO THE INDIANA
- 30 CODE AS A NEW SECTION TO READ AS FOLLOWS
- 31 [EFFECTIVE JULY 1, 2008]: Sec. 264.3. "Opioid treatment
- 32 program" means a program through which opioid agonist
- 33 medication is dispensed to an individual in the treatment of opiate
- 34 addiction and for which certification is required under 42 C.F.R.
- 35 8.
- 36 SECTION 13. IC 16-25.5 IS ADDED TO THE INDIANA CODE
- 37 AS A NEW ARTICLE TO READ AS FOLLOWS [EFFECTIVE JULY
- 38 1, 2008]:
- 39 **ARTICLE 25.5. OPIOID TREATMENT PROGRAM**
- 40 **FACILITIES**
- 41 **Chapter 1. General Provisions**
- 42 **Sec. 1. This article applies to all facilities in which an opioid**

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treatment program is operated.

Sec. 2. (a) The state department and the state health commissioner shall enforce this article.

(b) The state department or the state health commissioner may bring an action at law or in equity to enforce this article, and the circuit and superior courts of the state have jurisdiction to compel or enforce the provisions of this article by prohibitory or mandatory injunction.

Chapter 2. Licensure and Regulation of Opioid Treatment Program Facilities

Sec. 1. Not later than July 1, 2009, the state department shall license and regulate all facilities in which an opioid treatment program operates in Indiana.

Sec. 2. The state department shall adopt rules under IC 4-22-2 to do the following concerning opioid treatment program facilities:

- (1) Establish minimum licensure qualifications, including requirements for the following:
 - (A) Sanitation standards.
 - (B) Emergency equipment and procedures.
 - (C) Quality assurance standards.
 - (D) Certification under IC 12-23-18 of the opioid treatment program operated in the facility.
- (2) Prescribe the operating, supervision, and maintenance policies concerning opioid treatment program patient records.
- (3) Establish procedures for the issuance, renewal, denial, and revocation of licenses under this chapter. The rules adopted under this subdivision must address the following:
 - (A) The form and content of the license.
 - (B) The collection of an annual license fee.
- (4) Prescribe the procedures and standards for inspections.
- (5) Establish annual licensing fees in an amount sufficient to pay the cost of implementing this article.

Sec. 3. A:

- (1) person; or
- (2) state, county, or local governmental unit;

shall obtain a license under this chapter before establishing, advertising, or operating an opioid treatment program.

Sec. 4. (a) An applicant shall submit to the state department an application for a license on a form prescribed by the state department reflecting that the applicant is:

- (1) of reputable and responsible character; and
- (2) able to comply with the requirements of this chapter and

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federal law.

(b) An application must contain the following additional information:

- (1) The name of the applicant.
- (2) The location of the opioid treatment program facility.
- (3) The name of the person responsible for the opioid treatment program.
- (4) Other information required by the state department.

Sec. 5. An application must be accompanied by a licensing fee at the rate established by the state department under section 2 of this chapter.

Sec. 6. The state health commissioner may:

- (1) issue a license upon an application without further evidence; or
- (2) request additional information concerning an application and conduct an investigation to determine whether a license should be granted.

Sec. 7. A license issued under this chapter:

- (1) expires one (1) year after the date of issuance;
- (2) is not assignable or transferable;
- (3) is issued only for the opioid treatment program facility premises named in the application;
- (4) must be posted in a conspicuous place in the opioid treatment program facility; and
- (5) may be renewed each year upon the payment of a renewal fee at the rate established by the state department under section 2 of this chapter.

Sec. 8. (a) The state department shall conduct an annual licensure inspection of an opioid treatment program facility in accordance with rules adopted under this chapter. The state department shall conduct all health and sanitation inspections, including inspections in response to an alleged breach of this chapter. The division of fire and building safety shall make all fire safety inspections.

(b) An employee of the state department who knowingly or intentionally informs an individual who is involved in the operation of an opioid treatment program of the exact date of an unannounced inspection shall be suspended without pay for five (5) days for a first offense and shall be dismissed for a subsequent offense.

(c) A report of each inspection conducted under this section must be in writing and sent to the opioid treatment program.

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(d) A report of an inspection conducted under this section, and records relating to the inspection, may not be released to the public until the conditions set forth in IC 16-19-3-25 are satisfied.

Chapter 3. Violations

Sec. 1. The state health commissioner may take any of the following actions based on any ground described in section 2 of this chapter:

- (1) Issue a letter of correction.
- (2) Issue a probationary license.
- (3) Reinspect the opioid treatment program facility.
- (4) Deny renewal of a license.
- (5) Revoke a license.
- (6) Impose a civil penalty in an amount not to exceed ten thousand dollars (\$10,000).

Sec. 2. The state health commissioner may take action under section 1 of this chapter based on any of the following grounds:

- (1) Violation of this article or rules adopted under this article.
- (2) Permitting, aiding, or abetting the commission of any illegal act in an opioid treatment program facility.
- (3) Conduct or practice found by the state health commissioner to be detrimental to the welfare of an opioid treatment program patient.

Sec. 3. IC 4-21.5 applies to an action under this chapter.

Chapter 4. Penalties

Sec. 1. The state department shall investigate a report of an unlicensed opioid treatment program facility and report the findings to the attorney general. The attorney general may seek any of the following:

- (1) An injunction in a court of jurisdiction in the county in which the unlicensed opioid treatment program facility is established, advertised, or operated or in the circuit or superior court of Marion County.
- (2) Relief under IC 4-21.5, including a civil penalty not to exceed twenty-five thousand dollars (\$25,000) for each day of unlicensed operation.
- (3) Criminal penalties.

Sec. 2. A person who:

- (1) establishes;
- (2) advertises the operation of; or
- (3) operates;

an opioid treatment program facility that is not licensed under this article commits a Class A misdemeanor.

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1 SECTION 14. IC 12-23-18-6 IS REPEALED [EFFECTIVE JULY
2 1, 2008].

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