



January 25, 2008

SENATE BILL No. 157

DIGEST OF SB 157 (Updated January 23, 2008 2:38 pm - DI 104)

Citations Affected: IC 12-7; IC 12-23.

Synopsis: Opioid treatment programs. Changes the term "methadone treatment" to "opioid treatment" for purposes of the law concerning certification of opiate addiction treatment facilities. Requires the division of mental health and addiction to adopt rules on: (1) standards for operation of an opioid treatment program; (2) a requirement that the opioid treatment facilities submit a current diversion control plan; and (3) fees to be paid by an opioid treatment facility. 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, Sipes

January 8, 2008, read first time and referred to Committee on Health and Provider Services.
January 24, 2008, amended, reported favorably — Do Pass.

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SB 157—LS 6402/DI 97+



January 25, 2008

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 CFR**
7 **Part 8.**

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

- 12 (1) **the opioid treatment program is specifically approved and**
- 13 **the opiate treatment facility is certified by the division; and**
- 14 (2) **the opioid treatment program is in compliance with state**
- 15 **and federal law.**

16 (b) **Separate specific approval and certification under this**
17 **chapter is required for each location at which an opioid treatment**

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program is operated.

SECTION 3. IC 12-23-18-1 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 1. (a) Subject to federal law and consistent with standard medical practice in ~~methadone~~ **opioid** treatment of drug abuse, the division shall adopt rules under IC 4-22-2 to establish and administer ~~a methadone~~ **an opioid treatment** diversion control and oversight program to identify individuals who divert ~~controlled substances~~ **opioid treatment medications** from legitimate treatment use and to terminate the ~~methadone~~ **opioid** treatment of those individuals.

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

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

SECTION 4. IC 12-23-18-2 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 2. (a) Not later than February 28 of each year, each ~~methadone provider~~ **opioid treatment program** must submit to the division a diversion control plan ~~required under that meets the requirements of section 1(b)(7)~~ **1** of this 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 5. 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:~~ **that is:**

- (1) ~~twenty dollars (\$20) for each nonresident; patient~~ **an amount**

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1 **established by the division by rule under IC 4-22-2;**
 2 **(2) not more than necessary to recover the costs of**
 3 **administering this chapter; and**
 4 **(3) not more than seventy-five dollars (\$75) for each opioid**
 5 **treatment program patient, who was treated by the methadone**
 6 **provider opioid treatment program during the preceding**
 7 **calendar year.**

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

11 SECTION 6. IC 12-23-18-4 IS AMENDED TO READ AS
 12 FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 4. (a) As used in this
 13 section, "fund" means the ~~methadone opioid treatment diversion~~
 14 ~~control and oversight~~ program fund established under subsection (b).

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

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

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

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

25 SECTION 7. IC 12-23-18-5 IS AMENDED TO READ AS
 26 FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 5. **(a) The division**
 27 **shall adopt rules under IC 4-22-2 to establish the following:**

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

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

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

- 36 **(i) physical presence in the opioid treatment facility; and**
- 37 **(ii) physical evaluation and progress evaluation of each**
- 38 **opioid treatment program patient.**

39 **(C) Minimum staffing requirements by licensed and**
 40 **unlicensed personnel.**

41 **(D) Clinical standards for the appropriate tapering of a**
 42 **patient on and off of an opioid treatment medication.**

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1 (2) A requirement that, not later than February 28 of each
2 year, a current diversion control plan that meets the
3 requirements of 21 CFR Part 291 and 42 CFR Part 8 be
4 submitted for each opioid treatment facility.

5 (3) Fees to be paid by an opioid treatment program for
6 deposit in the fund for annual certification under this chapter
7 as described in section 3 of 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 8. 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 9. 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 10. 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, the state department of health, and to the governor a**
39 **report concerning treatment offered by opioid treatment**
40 **programs. The report must contain the following information for**
41 **each of the two (2) previous calendar 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 number of patients who were determined to be no**
- 9 **longer in need of services and are no longer receiving opioid**
- 10 **treatment.**
- 11 **(6) The number of individuals, by geographic area, who are**
- 12 **on a waiting list to receive opioid treatment.**
- 13 **(7) The patient information reported to the central registry**
- 14 **established under section 5.6 of this chapter.**
- 15 **(8) Any other information that the division determines to be**
- 16 **relevant to the success of a quality opioid treatment program.**
- 17 **(b) Each opioid treatment program in Indiana shall provide**
- 18 **information requested by the division for the report required by**
- 19 **this section.**
- 20 **(c) Failure of an opioid treatment program to submit the**
- 21 **information required under subsection (a) may result in suspension**
- 22 **or termination of the opioid treatment program's specific approval**
- 23 **to operate as an opioid treatment program or the opioid treatment**
- 24 **facility's certification.**
- 25 **(d) Information that could be used to identify an opioid**
- 26 **treatment program patient and that is:**
- 27 **(1) contained in; or**
- 28 **(2) provided to the division related to;**
- 29 **the report required by this section is confidential.**
- 30 **SECTION 11. IC 12-23-18-5.8 IS ADDED TO THE INDIANA**
- 31 **CODE AS A NEW SECTION TO READ AS FOLLOWS**
- 32 **[EFFECTIVE JULY 1, 2008]: Sec. 5.8. (a) The director of the**
- 33 **division may take any of the following actions based on any**
- 34 **grounds described in subsection (b):**
- 35 **(1) Issue a letter of correction.**
- 36 **(2) Reinspect the opioid treatment program facility.**
- 37 **(3) Deny renewal of, or revoke, any of the following:**
- 38 **(A) Specific approval to operate as an opioid treatment**
- 39 **program.**
- 40 **(B) Certification of the opioid treatment facility.**
- 41 **(4) Impose a civil penalty in an amount not to exceed ten**
- 42 **thousand dollars (\$10,000).**

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1 **(b) The director of the division may take action under**
2 **subsection (a) based on any of the following grounds:**
3 **(1) Violation of this chapter or rules adopted under this**
4 **chapter.**
5 **(2) Permitting, aiding, or abetting the commission of any**
6 **illegal act in an opioid treatment program facility.**
7 **(3) Conduct or practice found by the director to be**
8 **detrimental to the welfare of an opioid treatment program**
9 **patient.**
10 **(c) IC 4-21.5 applies to an action under this section.**
11 SECTION 12. IC 12-23-18-6 IS REPEALED [EFFECTIVE JULY
12 1, 2008].

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SENATE MOTION

Madam President: I move that Senator Sipes be added as second author of Senate Bill 157.

MILLER

 COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 157, 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:

Page 1, line 6, delete "C.F.R." and insert "**CFR Part**".

Page 1, delete lines 8 through 17.

Page 2, line 5, after "program" insert "**is specifically approved and the opiate treatment facility**".

Page 2, delete lines 6 through 7.

Page 2, line 9, delete "(3)" and insert "**(2)**".

Page 2, line 11, after "Separate" insert "**specific approval and**".

Page 3, line 10, strike "of:" and insert "**that is:**".

Page 3, line 11, strike "twenty dollars (\$20) for each".

Page 3, line 11, delete "resident; and".

Page 3, line 12, delete "(2) three hundred dollars (\$300) for each".

Page 3, line 12, strike "nonresident;".

Page 3, line 13, delete "of Indiana" and insert "**an amount established by the division by rule under IC 4-22-2;**

(2) not more than necessary to recover the costs of administering this chapter; and

(3) not more than seventy-five dollars (\$75) for each opioid treatment program patient."

Page 3, run in lines 11 through 13.

Page 3, line 20, strike "diversion".

Page 3, line 21, strike "control and oversight".

Page 3, line 22, strike "diversion control and".

Page 3, line 23, strike "oversight".

Page 4, between lines 5 and 6, begin a new line double block indented and insert:

"(D) Clinical standards for the appropriate tapering of a patient on and off of an opioid treatment medication."

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Page 4, line 6, after "(2)" insert **"A requirement that, not later than February 28 of each year, a current diversion control plan that meets the requirements of 21 CFR Part 291 and 42 CFR Part 8 be submitted for each opioid treatment facility.**

(3)".

Page 4, line 7, delete "chapter." and insert **"chapter as described in section 3 of this chapter."**

Page 4, line 38, after "IC 5-14-6" insert **", the state department of health,"**.

Page 5, delete lines 8 through 11.

Page 5, line 12, delete "(7)" and insert **"(5)".**

Page 5, line 12, delete "rehabilitated" and insert **"determined to be no longer in need of services".**

Page 5, line 14, delete "(8)" and insert **"(6)".**

Page 5, line 16, delete "(9)" and insert **"(7)".**

Page 5, between lines 17 and 18, begin a new line single block indented and insert:

"(8) Any other information that the division determines to be relevant to the success of a quality opioid treatment program."

Page 5, line 23, after "program's" insert **"specific approval to operate as an opioid treatment program or the opioid treatment facility's".**

Page 5, delete lines 29 through 42, begin a new paragraph and insert:

"SECTION 11. IC 12-23-18-5.8 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 5.8. (a) The director of the division may take any of the following actions based on any grounds described in subsection (b):

(1) Issue a letter of correction.

(2) Reinspect the opioid treatment program facility.

(3) Deny renewal of, or revoke, any of the following:

(A) Specific approval to operate as an opioid treatment program.

(B) Certification of the opioid treatment facility.

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

(b) The director of the division may take action under subsection (a) based on any of the following grounds:

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

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(2) Permitting, aiding, or abetting the commission of any illegal act in an opioid treatment program facility.

(3) Conduct or practice found by the director to be detrimental to the welfare of an opioid treatment program patient.

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

Delete pages 6 through 8.

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 157 as introduced.)

MILLER, Chairperson

Committee Vote: Yeas 11, Nays 0.

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