

**CONFERENCE COMMITTEE REPORT
DIGEST FOR ESB 157**

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

Synopsis: Opioid treatment programs. Conference committee report for ESB 157. 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. Requires an opioid treatment program to: (1) periodically and randomly test a patient for the use of specified drugs; and (2) take certain actions if the drug test is positive for an illegal drug other than the drug being used for the patient's treatment. Requires the division to create a central registry and prepare a biennial report. 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.) **(This conference committee report removes language requiring: (1) the office of the secretary of family and social services to form a nonprofit corporation to establish and operate an umbilical cord blood bank; and (2) suitable postnatal donations to be available for medical treatments and scientific research.)**

Effective: July 1, 2008.

CONFERENCE COMMITTEE REPORT

MADAM PRESIDENT:

Your Conference Committee appointed to confer with a like committee from the House upon Engrossed House Amendments to Engrossed Senate Bill No. 157 respectfully reports that said two committees have conferred and agreed as follows to wit:

that the Senate recede from its dissent from all House amendments and that the Senate now concur in all House amendments to the bill and that the bill be further amended as follows:

- 1 Delete everything after the enacting clause and insert the following:
2 SECTION 1. IC 12-7-2-135.6 IS ADDED TO THE INDIANA
3 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
4 [EFFECTIVE JULY 1, 2008]: **Sec. 135.6. "Opioid treatment**
5 **program" means a program through which opioid agonist**
6 **medication is dispensed to an individual in the treatment of opiate**
7 **addiction and for which certification is required under 42 CFR**
8 **Part 8.**
9 SECTION 2. IC 12-23-18-0.5 IS ADDED TO THE INDIANA
10 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
11 [EFFECTIVE JULY 1, 2008]: **Sec. 0.5. (a) An opioid treatment**
12 **program shall not operate in Indiana unless:**
13 **(1) the opioid treatment program is specifically approved and**
14 **the opiate treatment facility is certified by the division; and**
15 **(2) the opioid treatment program is in compliance with state**
16 **and federal law.**
17 **(b) Separate specific approval and certification under this**
18 **chapter is required for each location at which an opioid treatment**
19 **program is operated.**
20 SECTION 3. IC 12-23-18-1 IS AMENDED TO READ AS
21 FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 1. (a) Subject to federal
22 law and consistent with standard medical practice in ~~methadone~~ **opioid**

1 treatment of drug abuse, the division shall adopt rules under IC 4-22-2
 2 to establish and administer ~~a methadone~~ **an opioid treatment** diversion
 3 control and oversight program to identify individuals who divert
 4 ~~controlled substances~~ **opioid treatment medications** from legitimate
 5 treatment use and to terminate the ~~methadone~~ **opioid** treatment of those
 6 individuals.

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

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

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

- 28 (1) ~~meets the requirements of section 4(b)(7) 1~~ of this chapter;
 29 **and**
- 30 (2) **includes in the opioid treatment program's diversion**
 31 **control plan the program's drug testing procedure for testing**
 32 **a patient during the patient's treatment by the program as**
 33 **required by section 2.5 of this chapter.**

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

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

39 SECTION 5. IC 12-23-18-2.5 IS ADDED TO THE INDIANA
 40 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
 41 [EFFECTIVE JULY 1, 2008]: **Sec. 2.5. (a) An opioid treatment**
 42 **program must periodically and randomly test, including before**
 43 **receiving treatment, a patient for the following during the patient's**
 44 **treatment by the program:**

- 45 (1) **Methadone.**
- 46 (2) **Cocaine.**
- 47 (3) **Opiates.**
- 48 (4) **Amphetamines.**
- 49 (5) **Barbiturates.**
- 50 (6) **Tetrahydrocannabinol.**
- 51 (7) **Benzodiazepines.**

1 **(8) Any other suspected or known drug that may have been**
 2 **abused by the patient.**

3 **(b) If a patient tests positive under a test described in subsection**
 4 **(a) for:**

5 **(1) a controlled substance other than a drug for which the**
 6 **patient has a prescription or that is part of the patient's**
 7 **treatment plan at the opioid treatment program; or**

8 **(2) an illegal drug other than the drug that is part of the**
 9 **patient's treatment plan at the opioid treatment program;**
 10 **the opioid treatment program and the patient must comply with**
 11 **the requirements under subsection (c).**

12 **(c) If a patient tests positive under a test for a controlled**
 13 **substance or illegal drug that is not allowed under subsection (b),**
 14 **the following conditions must be met:**

15 **(1) The opioid treatment program must refer the patient to**
 16 **the onsite physician for a clinical evaluation that must be**
 17 **conducted not more than ten (10) days after the date of the**
 18 **patient's positive test. The physician shall consult with**
 19 **medical and behavioral staff to conduct the evaluation. The**
 20 **clinical evaluation must recommend a remedial action for the**
 21 **patient that may include discharge from the opioid treatment**
 22 **program or amending the treatment plan to require a higher**
 23 **level of supervision.**

24 **(2) The opioid treatment program may not allow the patient**
 25 **to take any opioid treatment medications from the treatment**
 26 **facility until the patient has completed a clinical assessment**
 27 **under subdivision (1) and has passed a random test. The**
 28 **patient must report to the treatment facility daily, except**
 29 **when the facility is closed, until the onsite physician, after**
 30 **consultation with the medical and behavioral staff, determines**
 31 **that daily treatment is no longer necessary.**

32 **(3) The patient must take a weekly random test until the**
 33 **patient passes a test under subsection (b).**

34 **(d) An opioid treatment program must conduct all tests**
 35 **required under this section in an observed manner to assure that**
 36 **a false sample is not provided by the patient.**

37 SECTION 6. IC 12-23-18-3 IS AMENDED TO READ AS
 38 FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 3. (a) By May 15 of
 39 each year, each ~~methadone~~ provider **opioid treatment program** shall
 40 submit to the division a fee of: ~~twenty dollars (\$20)~~ for each
 41 ~~nonresident;~~ **patient that is:**

42 **(1) an amount established by the division by rule under**
 43 **IC 4-22-2;**

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

46 **(3) not more than seventy-five dollars (\$75) for each opioid**
 47 **treatment program patient who was treated by the ~~methadone~~**
 48 **provider **opioid treatment program** during the preceding**
 49 **calendar year.**

50 (b) The fee collected under subsection (a) shall be deposited in the
 51 ~~methadone diversion control and oversight program fund.~~ **established**

1 under section 4 of this chapter.

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

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

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

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

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

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

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

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

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

27 **(i) physical presence in the opioid treatment facility; and**
28 **(ii) physical evaluation and progress evaluation of each**
29 **opioid treatment program patient.**

30 **(C) Minimum staffing requirements by licensed and**
31 **unlicensed personnel.**

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

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

38 **(3) Fees to be paid by an opioid treatment program for**
39 **deposit in the fund for annual certification under this chapter**
40 **as described in section 3 of this chapter.**

41 **The fees established under this subsection must be sufficient to pay**
42 **the cost of implementing this chapter.**

43 **(b) The division shall conduct an annual onsite visit of each**
44 **methadone provider opioid treatment program facility to assess**
45 **compliance with the plan approved under this chapter.**

46 SECTION 9. IC 12-23-18-5.5, AS ADDED BY P.L.210-2007,
47 SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
48 JULY 1, 2008]: Sec. 5.5. ~~(a)~~ The division may not grant specific
49 approval to be a new opioid treatment program. This section does not
50 apply to applications for new opioid treatment programs pending prior
51 to March 1, 2007.

1 (b) This section expires December 31, 2008.

2 SECTION 10. IC 12-23-18-5.6 IS ADDED TO THE INDIANA
3 CODE AS A NEW SECTION TO READ AS FOLLOWS
4 [EFFECTIVE JULY 1, 2008]: **Sec. 5.6. (a) The division shall**
5 **establish a central registry to maintain information concerning**
6 **each patient served by an opioid treatment program.**

7 **(b) An opioid treatment program shall, at least monthly, provide**
8 **to the division information required by the division concerning**
9 **patients currently served by the opioid treatment program.**

10 **(c) Information that could be used to identify an opioid**
11 **treatment program patient and that is:**

12 **(1) contained in; or**

13 **(2) provided to the division and related to;**

14 **the central registry is confidential.**

15 SECTION 11. IC 12-23-18-5.7 IS ADDED TO THE INDIANA
16 CODE AS A NEW SECTION TO READ AS FOLLOWS
17 [EFFECTIVE JULY 1, 2008]: **Sec. 5.7. (a) The division shall, as part**
18 **of the biennial report required under IC 12-21-5-1.5(8), prepare**
19 **and submit to the legislative council in an electronic format under**
20 **IC 5-14-6, the state department of health, and the governor a**
21 **report concerning treatment offered by opioid treatment**
22 **programs. The report must contain the following information for**
23 **each of the two (2) previous calendar years:**

24 **(1) The number of opioid treatment programs in Indiana.**

25 **(2) The number of patients receiving opioid treatment in**
26 **Indiana.**

27 **(3) The length of time each patient received opioid treatment**
28 **and the average length of time all patients received opioid**
29 **treatment.**

30 **(4) The cost of each patient's opioid treatment and the**
31 **average cost of opioid treatment.**

32 **(5) The number of patients who were determined to be no**
33 **longer in need of services and are no longer receiving opioid**
34 **treatment.**

35 **(6) The number of individuals, by geographic area, who are**
36 **on a waiting list to receive opioid treatment.**

37 **(7) The patient information reported to the central registry**
38 **established under section 5.6 of this chapter.**

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

41 **(9) The number of patients who tested positive under a test for**
42 **a controlled substance or illegal drug not allowed under**
43 **section 2.5(b) of this chapter.**

44 **(b) Each opioid treatment program in Indiana shall provide**
45 **information requested by the division for the report required by**
46 **this section.**

47 **(c) Failure of an opioid treatment program to submit the**
48 **information required under subsection (a) may result in suspension**
49 **or termination of the opioid treatment program's specific approval**
50 **to operate as an opioid treatment program or the opioid treatment**
51 **facility's certification.**

1 **(d) Information that could be used to identify an opioid**
 2 **treatment program patient and that is:**

3 **(1) contained in; or**

4 **(2) provided to the division related to;**

5 **the report required by this section is confidential.**

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

11 **(1) Issue a letter of correction.**

12 **(2) Reinspect an opioid treatment program facility.**

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

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

16 **(B) Certification of an opioid treatment facility.**

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

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

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

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

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

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

29 SECTION 13. IC 12-23-18-6 IS REPEALED [EFFECTIVE JULY
 30 1, 2008].

(Reference is to ESB 157 as reprinted February 27, 2008.)

Conference Committee Report
on
Engrossed Senate Bill 157

Signed by:

Senator Miller
Chairperson

Representative Stemler

Senator Sipes

Representative Brown T

Senate Conferees

House Conferees