

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.

SENATE ENROLLED ACT No. 157

AN ACT to amend the Indiana Code concerning health.

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

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

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

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

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



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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:~~

- (1) ~~meets the requirements of section 1(b)(7) 1~~ **meets the requirements of section 1 of this chapter;**
- and**
- (2) ~~includes in the opioid treatment program's diversion control plan the program's drug testing procedure for testing a patient during the patient's treatment by the program as required by section 2.5 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 12-23-18-2.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: **Sec. 2.5. (a) An opioid treatment program must periodically and randomly test, including before**

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receiving treatment, a patient for the following during the patient's treatment by the program:

- (1) Methadone.
- (2) Cocaine.
- (3) Opiates.
- (4) Amphetamines.
- (5) Barbiturates.
- (6) Tetrahydrocannabinol.
- (7) Benzodiazepines.
- (8) Any other suspected or known drug that may have been abused by the patient.

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

- (1) a controlled substance other than a drug for which the patient has a prescription or that is part of the patient's treatment plan at the opioid treatment program; or
 - (2) an illegal drug other than the drug that is part of the patient's treatment plan at the opioid treatment program;
- the opioid treatment program and the patient must comply with the requirements under subsection (c).

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

- (1) The opioid treatment program must refer the patient to the onsite physician for a clinical evaluation that must be conducted not more than ten (10) days after the date of the patient's positive test. The physician shall consult with medical and behavioral staff to conduct the evaluation. The clinical evaluation must recommend a remedial action for the patient that may include discharge from the opioid treatment program or amending the treatment plan to require a higher level of supervision.
- (2) The opioid treatment program may not allow the patient to take any opioid treatment medications from the treatment facility until the patient has completed a clinical assessment under subdivision (1) and has passed a random test. The patient must report to the treatment facility daily, except when the facility is closed, until the onsite physician, after consultation with the medical and behavioral staff, determines that daily treatment is no longer necessary.
- (3) The patient must take a weekly random test until the patient passes a test under subsection (b).

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

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: ~~twenty dollars (\$20) for each nonresident; patient that is:~~

- (1) 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 who was treated by the methadone provider opioid treatment program during the preceding 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 diversion control and oversight~~ **opioid treatment** program fund established under subsection (b).

(b) The ~~methadone diversion control and oversight~~ **opioid treatment** 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.**

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

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

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

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

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

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

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

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

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

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

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

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

- (1) contained in; or**
- (2) provided to the division and related to;**

the central registry is confidential.

SECTION 11. IC 12-23-18-5.7 IS ADDED TO THE INDIANA

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

- (1) The number of opioid treatment programs in Indiana.**
- (2) The number of patients receiving opioid treatment in Indiana.**
- (3) The length of time each patient received opioid treatment and the average length of time all patients received opioid treatment.**
- (4) The cost of each patient's opioid treatment and the average cost of opioid treatment.**
- (5) The number of patients who were determined to be no longer in need of services and are no longer receiving opioid treatment.**
- (6) The number of individuals, by geographic area, who are on a waiting list to receive opioid treatment.**
- (7) The patient information reported to the central registry established under section 5.6 of this chapter.**
- (8) Any other information that the division determines to be relevant to the success of a quality opioid treatment program.**
- (9) The number of patients who tested positive under a test for a controlled substance or illegal drug not allowed under section 2.5(b) of this chapter.**

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

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

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

- (1) contained in; or**
- (2) provided to the division related to;**

the report required by this section is confidential.

SECTION 12. IC 12-23-18-5.8 IS ADDED TO THE INDIANA

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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 an 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 an 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.**
- (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.

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

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President of the Senate

President Pro Tempore

Speaker of the House of Representatives

Governor of the State of Indiana

Date: _____ Time: _____

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