

IC 12-23-18

Chapter 18. Methadone Diversion Control and Oversight Program

IC 12-23-18-0.5

Opioid treatment program; requirements for operation

Sec. 0.5. (a) An opioid treatment program shall not operate in Indiana unless:

- (1) the opioid treatment program is specifically approved and the opioid 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.

As added by P.L.116-2008, SEC.2. Amended by P.L.1-2009, SEC.108.

IC 12-23-18-1

Rules

Sec. 1. (a) Subject to federal law and consistent with standard medical practice in opioid treatment of drug abuse, the division shall adopt rules under IC 4-22-2 to establish and administer an opioid treatment diversion control and oversight program to identify individuals who divert opioid treatment medications from legitimate treatment use and to terminate the opioid treatment of those individuals.

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

- (1) Regular clinic attendance by the patient.
- (2) Specific counseling requirements for the 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 opioid treatment program's medical director and administrative staff responsibilities for preparing and implementing a diversion control plan.

As added by P.L.11-2003, SEC.2. Amended by P.L.116-2008, SEC.3.

IC 12-23-18-2

Diversion control

Sec. 2. (a) Not later than February 28 of each year, each opioid treatment program must submit to the division a diversion control plan that:

- (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 a plan submitted under subsection (a).

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

As added by P.L.11-2003, SEC.2. Amended by P.L.116-2008, SEC.4.

IC 12-23-18-2.5

Drug testing

Sec. 2.5. (a) An opioid treatment program must periodically and randomly test, including before 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 (a), 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 (a).

(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.

As added by P.L.116-2008, SEC.5. Amended by P.L.131-2014, SEC.2.

IC 12-23-18-3

Opioid treatment program fees

Sec. 3. (a) By May 15 of each year, each opioid treatment program shall submit to the division a fee 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 opioid treatment program during the preceding calendar year.

(b) The fee collected under subsection (a) shall be deposited in the fund.

As added by P.L.11-2003, SEC.2. Amended by P.L.116-2008, SEC.6.

IC 12-23-18-4

Opioid treatment program fund

Sec. 4. (a) As used in this section, "fund" means the opioid treatment program fund established under subsection (b).

(b) The opioid treatment program fund is established to 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.

As added by P.L.11-2003, SEC.2. Amended by P.L.116-2008, SEC.7.

IC 12-23-18-5

Standards for operation; diversion control plans; annual compliance assessment; report

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 seven (7) days of opioid treatment medications at one (1) time and the division may approve the authorization only under the following circumstances:

(i) A physician licensed under IC 25-22.5 has issued an order for the opioid treatment medication.

(ii) The patient has not tested positive under a drug test for a drug for which the patient does not have a prescription for a period of time set forth by the division.

(iii) The opioid treatment program has determined that the benefit to the patient in receiving the take home opioid treatment medication outweighs the potential risk of diversion of the take home opioid treatment medication.

(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 opioid treatment program facility to assess compliance with this chapter.

(c) Not later than April 1 of each year, the division shall report to the general assembly in electronic format under IC 5-14-3 the number of prior authorizations that were approved under subsection (a)(1)(A) in the previous year and the time frame for each approval.

As added by P.L.11-2003, SEC.2. Amended by P.L.116-2008, SEC.8; P.L.131-2014, SEC.3.

IC 12-23-18-5.5

Prohibition of new opioid treatment program approval

Sec. 5.5. 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. *As added by P.L.210-2007, SEC.1. Amended by P.L.116-2008, SEC.9.*

IC 12-23-18-5.6

Central registry

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.

As added by P.L.116-2008, SEC.10.

IC 12-23-18-5.7

Repealed

(Repealed by P.L.28-2012, SEC.17.)

IC 12-23-18-5.8

Violations; penalties

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.

As added by P.L.116-2008, SEC.12.

IC 12-23-18-6

Repealed

(Repealed by P.L.116-2008, SEC.13.)

IC 12-23-18-7

Adoption of rules establishing standards and protocols; use of alternative medication for treatment; explanation of side effects

Sec. 7. (a) The division shall adopt rules under IC 4-22-2 to establish standards and protocols for opioid treatment programs to do the following:

(1) Assess new opioid treatment program patients to determine the most effective opioid treatment medications to start the

patient's opioid treatment.

(2) Ensure that each patient voluntarily chooses maintenance treatment and that relevant facts concerning the use of opioid treatment medications are clearly and adequately explained to the patient.

(3) Have appropriate opioid treatment program patients who are receiving methadone for opioid treatment move to receiving other approved opioid treatment medications.

(b) An opioid treatment program shall follow the standards and protocols adopted under subsection (a) for each opioid treatment program patient.

(c) Subject to subsection (a), an opioid treatment program may use any of the following medications as an alternative for methadone for opioid treatment:

(1) Buprenorphine.

(2) Buprenorphine combination products containing naloxone.

(3) Any other medication that has been approved by:

(A) the federal Food and Drug Administration for use in the treatment of opioid addiction; and

(B) the division under subsection (e).

(d) Before starting a patient on a new opioid treatment medication, the opioid treatment program shall explain to the patient the potential side effects of the new medication.

(e) The division may adopt rules under IC 4-22-2 to provide for other medications as alternatives to methadone that may be used under subsection (a).

As added by P.L.131-2014, SEC.4.

IC 12-23-18-8

"Dispense"; provision of information to division; annual report

Sec. 8. (a) As used in this section, "dispense" means to deliver a controlled substance to an ultimate user.

(b) Subject to the federal patient confidentiality requirements under 42 CFR Part 2, when an opioid treatment program dispenses a controlled substance designated by the Indiana board of pharmacy under IC 35-48-2-5 through 35-48-2-10, the opioid treatment program shall provide the following information upon request from the division:

(1) The medications dispensed by the program.

(2) The medication delivery process, which includes whether the medication was in liquid, film, or another form.

(3) The number of doses dispensed of each medication.

(4) The dosage quantities for each medication.

(5) The number of patients receiving take home medications.

(6) The number of days of supply dispensed.

(7) Patient demographic information for each medication, including gender, age, and time in treatment.

(8) The dispenser's United States Drug Enforcement Agency registration number.

(c) An opioid treatment program shall provide the information

required under this section to the division in a manner prescribed by the division.

(d) The division shall annually report the information collected under this section to the legislative council in an electronic format under IC 5-14-6 not later than October 1.

As added by P.L.131-2014, SEC.5.