SENATE BILL No. 439

DIGEST OF INTRODUCED BILL

Citations Affected: IC 12-15; IC 12-23-19.

Synopsis: Controlled substances. Prohibits the office of Medicaid policy and planning (office) from reimbursing under Medicaid for Subutex and Suboxone if the drug was prescribed for the treatment of pain management, and places limitations for these drugs when prescribed for Medicaid recipients for the treatment of substance abuse. Requires the office to compare Medicaid enrollment with the Indiana scheduled prescription electronic collection and tracking program (INSPECT) to identify Medicaid recipients who filled controlled substance prescriptions without using Medicaid. Requires the certification of opioid treatment providers, and sets forth requirements for these providers. Establishes the opioid treatment provider fund for purposes of administering opioid treatment provider certification.

Effective: July 1, 2015.

Hershman

January 20, 2015, read first time and referred to Committee on Health & Provider Services.

Introduced

First Regular Session 119th General Assembly (2015)

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 2014 Regular Session and 2014 Second Regular Technical Session of the General Assembly.

SENATE BILL No. 439

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

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

SECTION 1. IC 12-15-35-35 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 35. (a) **Except as provided in IC 12-15-35.5-9,** before the board develops a program to place a single source drug on prior approval, restrict the drug in its use, or establish a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must meet the following conditions:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Meet to review a formulary or a restriction on a single source

drug after the office provides at least fifteen (15) days notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:

(A) A statement of the date, time, and place at which the board meeting will be convened.

(B) A general description of the subject matter of the board meeting.

(C) An explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least fifteen (15) days but not more than sixty (60) days after the notification.

(3) Ensure that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and

(B) a process is in place through which a Medicaid recipient has access to medically necessary drugs.

(4) Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

(5) Ensure that the program provides either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

(6) Ensure that any prior approval program or restriction on the use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

(b) The board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

(c) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendations to the office.

SECTION 2. IC 12-15-35.5-9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: **Sec. 9. (a) The office may not**

reimburse under Medicaid for the following drugs or an equivalent or generic of the drug if the drug was prescribed for the treatment of pain or pain management:

(1) Subutex.

(2) Suboxone.

(b) The following apply to a prescription drug described in subsection (a) for a Medicaid recipient if the prescription is for the treatment of substance abuse:

(1) Prior authorization is not required for the initial prescription, and the prescription must be:

(A) treated as an initial prescription for a mental health drug; and

(B) documented in the Medicaid data base with the information concerning dispensing of the prescription drug.

(2) Except as provided in subdivision (3), the office may not reimburse for the prescription drug for more than six (6) months if the drug is prescribed for the treatment of substance abuse.

(3) The office may reimburse for the prescription drug for more than six (6) months for a Medicaid recipient only if:

(A) the drug is prescribed for the treatment of substance abuse; and

(B) the prescriber is either:

(i) treating as part of an opioid treatment program approved and certified under and meets the requirements of IC 12-23-18; or

(ii) certified under and meets the requirements of IC 12-23-19.

SECTION 3. IC 12-15-35.5-10 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: **Sec. 10. (a) Before March 1 of each year, the office shall, for the previous calendar year, compare a list of Medicaid recipients with entries in the Indiana scheduled prescription electronic collection and tracking (INSPECT) program established by IC 25-1-13-4 to identify any Medicaid recipient who filled a prescription for a controlled substance that was not reimbursed by Medicaid during the time that the individual was eligible to receive Medicaid reimbursement for the prescription.**

(b) The office shall review the information obtained under this section in identifying fraud, abuse, or overutilization of a

prescription drug under the Medicaid program by a Medicaid recipient.

SECTION 4. IC 12-23-19 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]:

Chapter 19. Opioid Treatment Provider Certification

Sec. 1. An opioid treatment provider shall not operate in Indiana unless:

(1) the opioid treatment provider is certified by the division; and

(2) the opioid treatment provider complies with state and federal law.

Sec. 2. (a) The division shall establish and administer a certification for opioid treatment providers.

(b) 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 concerning opioid treatment by an opioid treatment provider, including the following:

(1) Regular in person appointments between the patient and the opioid provider.

(2) Specific counseling requirements.

(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) Provider responsibilities for preparing and implementing a diversion control plan.

(c) Not later than February 28 of each year, an opioid treatment provider shall submit to the division a diversion control plan. The diversion control plan must:

(1) meet the requirements of this chapter; and

(2) include the provider's drug testing procedure for testing a patient during the patient's treatment by the program.

(d) Not later than May 1 of each year, the division shall review and determine whether to approve a plan submitted under subsection (c). If the division denies a plan submitted under this section, the opioid treatment provider must submit another plan not later than sixty (60) days after the denial of the plan.

Sec. 3. (a) An opioid treatment provider shall periodically and randomly test, including before receiving treatment, a patient for

the following during the patient's treatment by the provider:

(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 with the provider; or

(2) an illegal drug other than the drug that is part of the patient's treatment plan with the provider;

the opioid treatment provider and the patient shall 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 provider shall perform a clinical evaluation not more than ten (10) days after the date of the patient's positive test. The physician shall consult with behavioral staff to conduct the evaluation. The clinical evaluation must recommend a remedial action for the patient that may include termination of treatment by the provider or require a higher level of supervision.

(2) The opioid treatment provider may not allow the patient to take any opioid treatment medications from the provider's office until the patient has completed a clinical evaluation under subdivision (1) and has passed a random drug test. The patient shall report to the provider's office daily, except when the provider's office is closed, until the provider determines that daily treatment is no longer necessary.

(3) The patient shall take a weekly random drug test until the patient passes a test under subsection (a).

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

Sec. 4. (a) The opioid provider treatment fund is established to

implement this chapter. The fund shall be administered by the division.

(b) Before May 15 of each year, each opioid treatment provider shall submit to the division a fee that is:

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

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

The division shall deposit the collected fees in the fund established under subsection (a).

(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.

Sec. 5. (a) The division shall adopt rules under IC 4-22-2 to establish the following:

(1) A requirement that an opioid treatment provider obtain prior authorization from the division for any patient receiving more than seven (7) days of opioid treatment medications at one (1) time and that the division may approve the authorization only under the following circumstances:

(A) An opioid treatment provider registered under this chapter has issued an order for the opioid treatment medication.

(B) 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 set forth by the division.

(C) The opioid treatment provider 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.

(2) Minimum requirements for an opioid treatment provider's regular physical evaluation and progress evaluation of each opioid treatment patient.

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

(4) Fees to be paid by an opioid treatment provider for certification under this chapter and for deposit in the fund established under section 4 of this chapter.

(5) Standards and protocols for an opioid treatment provider

to do the following:

(A) Assess new opioid treatment patients to determine the most effective opioid treatment medications to start the patient's opioid treatment.

(B) 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.

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

(b) The division may use the rules adopted under IC 12-23-18-5 or IC 12-23-18-7 to satisfy the requirements of subsection (a) if the division determines that the rules meet the standards and requirements of subsection (a).

Sec. 6. The division may conduct an annual onsite visit of an opioid treatment provider's facility to assess compliance with this chapter.

Sec. 7. (a) An opioid treatment provider shall, at least monthly, provide to the division information required by the division concerning patients currently served by the opioid treatment provider.

(b) The division shall maintain the information provided under subsection (a) in the central registry maintained by the division under IC 12-23-18-5.6.

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

(1) contained in; or

(2) provided to the division and related to;

the central registry is confidential.

Sec. 8. (a) This section is subject to the federal patient confidentiality requirements under 42 CFR Part 2.

(b) If an opioid treatment provider dispenses a controlled substance designated by the Indiana board of pharmacy under IC 35-48-2-5 through IC 35-48-2-10, the opioid treatment provider shall provide the following information upon request from the division:

(1) The medications dispensed by the provider.

(2) The medication delivery process, including 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 provider shall provide the information required under this section to the division in a manner prescribed by the division.

(d) The division shall include the information collected under this section in the report required in IC 12-23-18-8(d).

Sec. 9. (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 provider's facility.

(3) Deny renewal of, or revoke certification of an opioid treatment provider.

(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 provider's 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.