



January 22, 2016

SENATE BILL No. 297

DIGEST OF SB 297 (Updated January 20, 2016 1:03 pm - DI 104)

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

Synopsis: Opioid dependence treatment. Requires Medicaid coverage for inpatient detoxification for the treatment of opioid or alcohol dependence. Specifies that the healthy Indiana plan includes coverage of counseling services for substance abuse treatment. Adds requirements for an opioid treatment program to meet in order to operate in Indiana. Requires the division of mental health and addiction (division) to adopt specified administrative rules concerning opioid treatment by an opioid treatment provider. Requires the office of the secretary and the division to develop treatment protocol containing best practice guidelines for the treatment of opiate dependent patients. Requires an opioid treatment program to provide specified information upon request by the division.

Effective: July 1, 2016.

**Miller Patricia, Becker, Mrvan,
Merritt, Stoops**

January 7, 2016, read first time and referred to Committee on Health & Provider Services.
January 21, 2016, amended, reported favorably — Do Pass.

SB 297—LS 6841/DI 104



January 22, 2016

Second Regular Session 119th General Assembly (2016)

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 2015 Regular Session of the General Assembly.

SENATE BILL No. 297

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:

- 1 SECTION 1. IC 12-15-5-13, AS ADDED BY P.L.209-2015,
2 SECTION 11, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
3 JULY 1, 2016]: Sec. 13. (a) The office shall provide coverage for
4 treatment of opioid or alcohol dependence that includes the following:
5 (1) Counseling services that address the psychological and
6 behavioral aspects of addiction.
7 (2) When medically indicated, drug treatment involving agents
8 approved by the federal Food and Drug Administration for the:
9 (A) treatment of opioid or alcohol dependence; or
10 (B) prevention of relapse to opioids or alcohol after
11 detoxification.
12 **(3) Inpatient detoxification:**
13 **(A) in accordance with the most current edition of the**
14 **American Society of Addiction Medicine Patient Placement**
15 **Criteria; and**
16 **(B) when determined by the treatment plan to be medically**
17 **necessary.**

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1 (b) The office shall:

2 (1) develop quality measures to ensure; and

3 (2) require a Medicaid managed care organization to report;
4 compliance with the coverage required under subsection (a).

5 (c) The office may implement quality capitation withholding of
6 reimbursement to ensure that a Medicaid managed care organization
7 has provided the coverage required under subsection (a).

8 (d) The office shall report the clinical use of the medications
9 covered under this section to the mental health Medicaid quality
10 advisory committee established by IC 12-15-35-51. The mental health
11 Medicaid quality advisory committee may make recommendations to
12 the office concerning this section.

13 SECTION 2. IC 12-15-35-35 IS AMENDED TO READ AS
14 FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 35. (a) **Except as**
15 **provided in IC 12-15-35.5-9**, before the board develops a program to
16 place a single source drug on prior approval, restrict the drug in its use,
17 or establish a drug monitoring process or program to measure or restrict
18 utilization of single source drugs other than in the SURS program, the
19 board must meet the following conditions:

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

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

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

28 (2) Meet to review a formulary or a restriction on a single source
29 drug after the office provides at least fifteen (15) days notification
30 to the public that the board will review the formulary or
31 restriction on a single source drug at a particular board meeting.

32 The notification shall contain the following information:

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

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

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

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

42 (3) Ensure that:

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- 1 (A) there is access to at least two (2) alternative drugs within
 2 each therapeutic classification, if available, on the formulary;
 3 and
 4 (B) a process is in place through which a Medicaid recipient
 5 has access to medically necessary drugs.
- 6 (4) Reconsider the drug's removal from its restricted status or
 7 from prior approval not later than six (6) months after the single
 8 source drug is placed on prior approval or restricted in its use.
- 9 (5) Ensure that the program provides either telephone or FAX
 10 approval or denial Monday through Friday, twenty-four (24) hours
 11 a day. The office must provide the approval or denial within
 12 twenty-four (24) hours after receipt of a prior approval request.
 13 The program must provide for the dispensing of at least a
 14 seventy-two (72) hour supply of the drug in an emergency
 15 situation or on weekends.
- 16 (6) Ensure that any prior approval program or restriction on the
 17 use of a single source drug is not applied to prevent acceptable
 18 medical use for appropriate off-label indications.
- 19 (b) The board shall advise the office on the implementation of any
 20 program to restrict the use of brand name multisource drugs.
- 21 (c) The board shall consider:
- 22 (1) health economic data;
 23 (2) cost data; and
 24 (3) the use of formularies in the non-Medicaid markets;
 25 in developing its recommendations to the office.
- 26 SECTION 3. IC 12-15-44.2-4, AS AMENDED BY P.L.209-2015,
 27 SECTION 13, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 28 JULY 1, 2016]: Sec. 4. (a) The plan must include the following in a
 29 manner and to the extent determined by the office:
- 30 (1) Mental health care services.
 31 (2) Inpatient hospital services.
 32 (3) Prescription drug coverage, including coverage of a long
 33 acting, nonaddictive medication assistance treatment drug if the
 34 drug is being prescribed for the treatment of substance abuse.
 35 (4) Emergency room services.
 36 (5) Physician office services.
 37 (6) Diagnostic services.
 38 (7) Outpatient services, including therapy services.
 39 (8) Comprehensive disease management.
 40 (9) Home health services, including case management.
 41 (10) Urgent care center services.
 42 (11) Preventative care services.



- 1 (12) Family planning services:
 2 (A) including contraceptives and sexually transmitted disease
 3 testing, as described in federal Medicaid law (42 U.S.C. 1396
 4 et seq.); and
 5 (B) not including abortion or abortifacients.
 6 (13) Hospice services.
 7 (14) Substance abuse services, **including counseling services**
 8 **described in IC 25-23.6-1-5.9.**
 9 (15) A service determined by the secretary to be required by
 10 federal law as a benchmark service under the federal Patient
 11 Protection and Affordable Care Act.
 12 (b) The plan may do the following:
 13 (1) Offer coverage for dental and vision services to an individual
 14 who participates in the plan.
 15 (2) Pay at least fifty percent (50%) of the premium cost of dental
 16 and vision services coverage described in subdivision (1).
 17 (c) An individual who receives the dental or vision coverage offered
 18 under subsection (b) shall pay an amount determined by the office for
 19 the coverage. The office shall limit the payment to not more than five
 20 percent (5%) of the individual's annual household income. The
 21 payment required under this subsection is in addition to the payment
 22 required under section 11(b)(2) of this chapter for coverage under the
 23 plan.
 24 (d) Vision services offered by the plan must include services
 25 provided by an optometrist.
 26 (e) The plan must comply with any coverage requirements that
 27 apply to an accident and sickness insurance policy issued in Indiana.
 28 (f) The plan may not permit treatment limitations or financial
 29 requirements on the coverage of mental health care services or
 30 substance abuse services if similar limitations or requirements are not
 31 imposed on the coverage of services for other medical or surgical
 32 conditions.
 33 SECTION 4. IC 12-23-18-0.5, AS AMENDED BY P.L.1-2009,
 34 SECTION 108, IS AMENDED TO READ AS FOLLOWS
 35 [EFFECTIVE JULY 1, 2016]: Sec. 0.5. (a) An opioid treatment
 36 program shall not operate in Indiana unless **the opioid treatment**
 37 **program meets the following conditions:**
 38 (1) ~~the opioid treatment program~~ Is specifically approved and the
 39 opioid treatment facility is certified by the division. ~~and~~
 40 (2) ~~the opioid treatment program~~ Is in compliance with state and
 41 federal law.
 42 (3) **Provides treatment for opioid addiction using a drug**



1 approved by the federal Food and Drug Administration for
2 the treatment of opioid addiction, including:

- 3 (A) opioid maintenance;
4 (B) detoxification;
5 (C) overdose reversal;
6 (D) relapse prevention; and
7 (E) long acting, nonaddictive medication assisted treatment
8 medications.

9 (4) Is, before December 31, 2016:

- 10 (A) enrolled as a Medicaid provider under IC 12-15;
11 (B) enrolled as a healthy Indiana plan provider under
12 IC 12-15-44.2; and
13 (C) a provider credentialed to accept insurance from a
14 health plan (as defined in IC 4-1-12-2), including:
15 (i) a policy of accident and sickness insurance
16 (IC 27-8-5); and
17 (ii) a health maintenance organization (IC 27-13).

18 (b) Separate specific approval and certification under this chapter
19 is required for each location at which an opioid treatment program is
20 operated. **If an opioid treatment program moves the opioid
21 treatment program's facility to another location, the opioid
22 treatment program's certification does not apply to the new
23 location and certification for the new location under this chapter
24 is required.**

25 SECTION 5. IC 12-23-18-5, AS AMENDED BY P.L.7-2015,
26 SECTION 38, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
27 JULY 1, 2016]: Sec. 5. (a) The division shall adopt rules under
28 IC 4-22-2 to establish the following:

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

31 (A) An opioid treatment program shall obtain prior
32 authorization from the division for any patient receiving more
33 than seven (7) days of opioid **maintenance** treatment
34 medications at one (1) time and the division may approve the
35 authorization only under the following circumstances:

- 36 (i) A physician licensed under IC 25-22.5 has issued an
37 order for the opioid treatment medication.
38 (ii) The patient has not tested positive under a drug test for
39 a drug for which the patient does not have a prescription for
40 a period of time set forth by the division.
41 (iii) The opioid treatment program has determined that the
42 benefit to the patient in receiving the take home opioid



- 1 treatment medication outweighs the potential risk of
 2 diversion of the take home opioid treatment medication.
- 3 (B) Minimum requirements for a licensed physician's regular:
 4 (i) physical presence in the opioid treatment facility; and
 5 (ii) physical evaluation and progress evaluation of each
 6 opioid treatment program patient.
- 7 (C) Minimum staffing requirements by licensed and
 8 unlicensed personnel.
- 9 (D) Clinical standards for the appropriate tapering of a patient
 10 on and off of an opioid treatment medication.
- 11 (2) A requirement that, not later than February 28 of each year, a
 12 current diversion control plan that meets the requirements of 21
 13 CFR Part 290 and 42 CFR Part 8 be submitted for each opioid
 14 treatment facility.
- 15 (3) Fees to be paid by an opioid treatment program for deposit in
 16 the fund for annual certification under this chapter as described
 17 in section 3 of this chapter.
- 18 The fees established under this subsection must be sufficient to pay the
 19 cost of implementing this chapter.
- 20 (b) The division shall conduct an annual onsite visit of each opioid
 21 treatment program facility to assess compliance with this chapter.
- 22 (c) Not later than April 1 of each year, the division shall report to
 23 the general assembly in electronic format under ~~IC 5-14-3~~ **IC 5-14-6**
 24 the number of prior authorizations that were approved under subsection
 25 (a)(1)(A) in the previous year and the time frame for each approval.
- 26 SECTION 6. IC 12-23-18-5.3 IS ADDED TO THE INDIANA
 27 CODE AS A NEW SECTION TO READ AS FOLLOWS
 28 [EFFECTIVE JULY 1, 2016]: **Sec. 5.3. Subject to federal law and**
 29 **consistent with standard medical practices in opioid treatment for**
 30 **substance abuse, the division shall adopt rules under IC 4-22-2**
 31 **concerning opioid treatment by an opioid treatment provider,**
 32 **including the following:**
- 33 (1) **A requirement that the opioid treatment provider**
 34 **periodically review with the patient the patient's treatment**
 35 **plan. In the review, the opioid treatment provider shall**
 36 **consider changes to the plan with the goal of requiring the**
 37 **minimal clinically necessary medication dose, including, when**
 38 **appropriate, the goal of opioid abstinence.**
- 39 (2) **Treatment protocols containing best practice guidelines**
 40 **for the treatment of opiate dependent patients, including the**
 41 **following:**
- 42 (A) **Appropriate clinical use of all drugs approved by the**



1 federal Food and Drug Administration for the treatment
2 of opioid addiction, including the following when available:

3 (i) Opioid maintenance.

4 (ii) Detoxification.

5 (iii) Overdose reversal.

6 (iv) Relapse prevention.

7 (v) Long acting, nonaddictive medication assisted
8 treatment medications.

9 (B) Requirement of initial and periodic behavioral health
10 assessments for each patient.

11 (C) Appropriate use of providing overdose reversal,
12 relapse prevention, counseling, and ancillary services.

13 (D) Transitioning off agonist and partial agonist therapies
14 with the goal, when appropriate, of opioid abstinence.

15 (E) Training and experience requirements for providers
16 who treat and manage opiate dependent patients.

17 (F) Requirement that a provider who prescribes opioid
18 medication for a patient periodically review INSPECT (as
19 defined in IC 35-48-7-5.2) concerning controlled substance
20 information for the patient.

21 SECTION 7. IC 12-23-18-7.5 IS ADDED TO THE INDIANA
22 CODE AS A NEW SECTION TO READ AS FOLLOWS
23 [EFFECTIVE JULY 1, 2016]: **Sec. 7.5. The office of the secretary
24 and the division shall develop a treatment protocol containing best
25 practice guidelines for the treatment of opiate dependent patients.
26 The treatment protocol must require the minimal clinically
27 necessary medication dose, including, when appropriate, the goal
28 of opioid abstinence, and including the following:**

29 (1) **Appropriate clinical use of any drug approved by the
30 federal Food and Drug Administration for the treatment of
31 opioid addiction, including the following:**

32 (A) Opioid maintenance.

33 (B) Opioid detoxification.

34 (C) Overdose reversal.

35 (D) Relapse prevention.

36 (E) Long acting, nonaddictive medication assisted
37 treatment medications.

38 (2) **A requirement for initial and periodic behavioral health
39 assessments for each patient.**

40 (3) **Appropriate use of providing overdose reversal, relapse
41 prevention, counseling, and ancillary services.**

42 (4) **Transitioning off agonist and partial agonist therapies,**



1 when appropriate, with the goal of opioid abstinence.

2 **(5) Training and experience requirements for prescribers of**
 3 **drugs described in subdivision (1) in the treatment and**
 4 **management of opiate dependent patients.**

5 **(6) A requirement that prescribers obtain informed consent**
 6 **from a patient concerning all available opioid treatment**
 7 **options, including each option's potential benefits and risks,**
 8 **before prescribing a drug described in subdivision (1).**

9 SECTION 8. IC 12-23-18-8, AS ADDED BY P.L.131-2014,
 10 SECTION 5, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 11 JULY 1, 2016]: Sec. 8. (a) As used in this section, "dispense" means to
 12 deliver a controlled substance to an ultimate user.

13 (b) Subject to the federal patient confidentiality requirements under
 14 42 CFR Part 2, when an opioid treatment program dispenses a
 15 controlled substance designated by the Indiana board of pharmacy
 16 under IC 35-48-2-5 through 35-48-2-10, the opioid treatment program
 17 shall provide the following information upon request from the division:

18 (1) The medications dispensed by the program.

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

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

22 (4) The dosage quantities for each medication.

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

24 (6) The number of days of supply dispensed.

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

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

29 **(9) The average number of patients served by:**

30 **(A) the opioid treatment program annually; and**

31 **(B) each employed or contracted prescriber of the opioid**
 32 **treatment program.**

33 **(10) The annual ratio of employed or contracted prescribers**
 34 **to patients service at each opioid treatment program.**

35 **(11) The number of patients and the average length of**
 36 **treatment for each medication dispensed by the opioid**
 37 **treatment program.**

38 **(12) The number of patients completing an opiate treatment**
 39 **program treatment service having transitioned to opioid**
 40 **abstinence, including the use of long acting, nonaddictive**
 41 **medication for relapse prevention.**

42 **(13) The number of patients demonstrating improvement in**



1 **functioning, as defined by the division, while in treatment at**
2 **an opiate treatment program.**

3 **(14) An annual submission of each opiate treatment**
4 **program's policy concerning:**

5 **(A) the use of INSPECT (as defined in IC 35-48-7-5.2);**

6 **(B) the protocol for addressing patients who are found,**
7 **using INSPECT data, to have prescriptions for a controlled**
8 **substance, including benzodiazepines or other opiate**
9 **medications; and**

10 **(C) the protocol for addressing patients who have illicit**
11 **urine drug screens indicating the use of a controlled**
12 **substance, including benzodiazepines or other opiates,**
13 **whether prescribed or not.**

14 (c) An opioid treatment program shall provide the information
15 required under this section to the division in a manner prescribed by
16 the division.

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



COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 297, 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 2, line 12, delete ", including the development of a" and insert ". "

Page 2, delete lines 13 through 38.

Page 4, delete lines 10 through 32.

Page 6, line 16, delete "Is:" and insert "**Is, before December 31, 2016:**".

Page 8, line 1, delete ", when appropriate," and insert "**of requiring the minimal clinically necessary medication dose, including, when appropriate, the goal**".

Page 8, between lines 26 and 27, begin a new paragraph and insert:
 "SECTION 8. IC 12-23-18-7.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 7.5. The office of the secretary and the division shall develop a treatment protocol containing best practice guidelines for the treatment of opiate dependent patients. The treatment protocol must require the minimal clinically necessary medication dose, including, when appropriate, the goal of opioid abstinence, and including the following:**

- (1) **Appropriate clinical use of any drug approved by the federal Food and Drug Administration for the treatment of opioid addiction, including the following:**
 - (A) **Opioid maintenance.**
 - (B) **Opioid detoxification.**
 - (C) **Overdose reversal.**
 - (D) **Relapse prevention.**
 - (E) **Long acting, nonaddictive medication assisted treatment medications.**
- (2) **A requirement for initial and periodic behavioral health assessments for each patient.**
- (3) **Appropriate use of providing overdose reversal, relapse prevention, counseling, and ancillary services.**
- (4) **Transitioning off agonist and partial agonist therapies, when appropriate, with the goal of opioid abstinence.**
- (5) **Training and experience requirements for prescribers of drugs described in subdivision (1) in the treatment and management of opiate dependent patients.**



(6) A requirement that prescribers obtain informed consent from a patient concerning all available opioid treatment options, including each option's potential benefits and risks, before prescribing a drug described in subdivision (1)."

Page 9, line 6, delete ";" and insert "annually;"

Page 9, line 9, after "(10)" insert "**The annual ratio of employed or contracted prescribers to patients service at each opioid treatment program.**

(11)".

Page 9, line 12, delete "(11)" and insert "(12)".

Page 9, line 12, delete "successfully transitioned to" and insert "**completing an opiate treatment program treatment service having transitioned to opioid abstinence, including the use of long acting, nonaddictive medication for relapse prevention.**"

Page 9, delete lines 13 through 18, begin a new line block indented and insert:

"(13) The number of patients demonstrating improvement in functioning, as defined by the division, while in treatment at an opiate treatment program.

(14) An annual submission of each opiate treatment program's policy concerning:

(A) the use of INSPECT (as defined in IC 35-48-7-5.2);

(B) the protocol for addressing patients who are found, using INSPECT data, to have prescriptions for a controlled substance, including benzodiazepines or other opiate medications; and

(C) the protocol for addressing patients who have illicit urine drug screens indicating the use of a controlled substance, including benzodiazepines or other opiates, whether prescribed or not."

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 297 as introduced.)

MILLER PATRICIA, Chairperson

Committee Vote: Yeas 6, Nays 2.

