Reprinted
February 27, 2008

ENGROSSED
SENATE BILL No. 157

DIGEST OF SB 157 (Updated February 26, 2008 8:36 pm - DI 77)

Citations Affected: IC 12-7; IC 12-23; IC 12-31; IC 16-18; IC 16-21; noncode.

Synopsis: Health programs. 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.
(Continued next page)

Effective: July 1, 2008.

Miller, Sipes
(HOUSE SPONSORS — STEMLER, BUELL, GOODIN, BROWN C)

January 8, 2008, read first time and referred to Committee on Health and Provider Services.
January 24, 2008, amended, reported favorably — Do Pass.
January 28, 2008, read second time, ordered engrossed. Engrossed.
January 29, 2008, read third time, passed. Yeas 48, nays 0.

HOUSE ACTION

January 30, 2008, read first time and referred to Committee on Public Health.
February 21, 2008, amended, reported — Do Pass.
February 26, 2008, read second time, amended, ordered engrossed.

Digest Continued

Requires the division to create a central registry and prepare a biennial report. Specifies violations and penalties. Requires the office of the secretary of family and social services to form a nonprofit corporation to establish and operate an umbilical cord blood bank. Requires suitable postnatal donations to be available for medical treatments and scientific research. Requires the nonprofit corporation to develop a process for physicians, nurse midwives, and participating hospitals to inform pregnant patients of the option to make postnatal donations following delivery of a newborn infant. Requires the nonprofit corporation to establish an umbilical cord blood donation initiative to promote public awareness concerning the medical benefits of umbilical cord blood. 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.)

Reprinted
February 27, 2008

Second Regular Session 115th General Assembly (2008)

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.

ENGROSSED
SENATE BILL No. 157

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

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

SECTION 1. IC 12-7-2-118.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: **Sec. 118.3. "Initiative", for purposes of IC 12-31-2, has the meaning set forth in IC 12-31-2-1.**

SECTION 2. IC 12-7-2-132.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: **Sec. 132.5. "Nonprofit corporation", for purposes of IC 12-31, has the meaning set forth in IC 12-31-1-1.**

SECTION 3. 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 4. IC 12-7-2-142.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS

[EFFECTIVE JULY 1, 2008]: **Sec. 142.7. "Postnatal donation", for purposes of IC 12-31, has the meaning set forth in IC 12-31-1-2.**

SECTION 5. 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 6. 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** 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 7. 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** 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 8. 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 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 from 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).

(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 9. 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.~~ **that is:**

(1) ~~twenty dollars ($20) for each nonresident; patient~~ **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 ~~calender~~ **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 10. 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~~ **opioid treatment** ~~diversion control and oversight~~ program fund established under subsection (b).

(b) The ~~methadone~~ **opioid treatment** ~~diversion control and oversight~~ 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 11. 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.

(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 12. 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 13. 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 14. IC 12-23-18-5.7 IS ADDED TO THE INDIANA 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 to 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 15. IC 12-23-18-5.8 IS ADDED TO THE INDIANA 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 the 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 the 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 16. IC 12-31 IS ADDED TO THE INDIANA CODE AS A **NEW** ARTICLE TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]:

ARTICLE 31. UMBILICAL CORD BLOOD

Chapter 1. Public Umbilical Cord Blood Bank

Sec. 1. As used in this article, "nonprofit corporation" refers to the Indiana nonprofit corporation formed by the office of the secretary under section 3 of this chapter to establish and operate a public umbilical cord blood bank.

Sec. 2. As used in this article, "postnatal donation" means any of the following donations by a patient to the public umbilical cord blood bank:

(1) Postnatal fluid, including umbilical cord blood.

(2) Postnatal tissue, including the placenta and tissue extracted from an umbilical cord.

Sec. 3. (a) The office of the secretary shall form a nonprofit corporation to establish and provide for the operation of a public umbilical cord blood bank to promote public health and to exercise other essential governmental functions.

(b) The office of the secretary shall adopt rules under IC 4-22-2 concerning the protection of individual identifiable health information regarding the operation of the public umbilical cord blood bank.

Sec. 4. (a) The board of directors of the nonprofit corporation consists of the following:

(1) The state health commissioner or the commissioner's designee.

(2) The secretary or the secretary's designee.

(3) The secretary of commerce appointed under IC 5-28-3-4 or the secretary's designee.

(4) The director of the state department of health's office of minority health.

(5) The following individuals appointed by the governor:

(A) One (1) president or chief executive officer of an Indiana based hospital.

(B) One (1) research scientist with expertise in umbilical cord blood research.

(C) One (1) ethicist with expertise in bioethics.

(D) One (1) physician licensed under IC 25-22.5 who specializes in birthing and delivery.

(E) One (1) representative of a donor umbilical cord blood bank facility.

(F) One (1) member of the interagency state council on black and minority health established under IC 16-46-6.

(b) The board of directors shall appoint an advisory board. At least fifty-one percent (51%) of the advisory board members must be research scientists with expertise in stem cell research.

(c) The advisory board, using criteria established by the board of directors, is responsible for reviewing applications from research scientists, research institutions, and other persons interested in receiving a postnatal donation that is ineligible for transplant use from the public umbilical cord blood bank.

(d) The board of directors may contract with a person to perform the management and administrative operations of the public umbilical cord blood bank. The person shall follow the federal Food and Drug Administration's current good tissue practices.

(e) Subject to approval by the budget agency, the board of directors may, without the approval of the attorney general, employ legal counsel, technical experts, and other officers, agents, and employees that the board of directors considers necessary to carry out the efficient operation of a public umbilical cord blood bank.

(f) The board of directors shall determine the terms and conditions of the participating agreement that is executed with each participating hospital.

Sec. 5. The nonprofit corporation shall do the following:

(1) Establish procedures and guidelines for collecting, maintaining, and receiving postnatal donations.

(2) Educate health care professionals about the procedures and requirements for collecting and maintaining postnatal donations following the birth of a newborn infant.

(3) Establish procedures concerning patient informed consent and privacy that are approved by an independent institutional review board selected by the board of directors.

Sec. 6. (a) The nonprofit corporation shall accept postnatal donations at no charge or cost to the donor.

(b) The nonprofit corporation may allow the following to use the postnatal donations:

(1) Transplant centers.

(2) Research centers approved by the nonprofit corporation that will use the postnatal donation to promote medical advances, life science research, or biotechnology research.

(3) Any other entity approved by the nonprofit corporation if the entity will use the postnatal donation to promote medical advances, life science research, or biotechnology research.

(c) Any postnatal donations maintained by the public umbilical cord blood bank must be allocated as follows:

(1) Postnatal donations that are of transplantable quality

according to the National Marrow Donor Program, the federal Food and Drug Administration's approved protocol, or other relevant national practice and quality standards must be allocated for medical transplants.

(2) Postnatal donations that do not meet the transplant quality standards referred to in subdivision (1) and that are suitable for research must be made available for scientific research or medical treatments that comply with relevant national practice and quality standards.

(d) The nonprofit corporation shall acquire and maintain adequate liability insurance coverage.

Sec. 7. The nonprofit corporation may maintain postnatal donations at no charge or cost to the donor.

Sec. 8. The nonprofit corporation may award a grant to a person for work with postnatal donations.

Sec. 9. The nonprofit corporation shall report annually to the health finance commission established by IC 2-5-23-3 concerning the following:

(1) The implementation of the umbilical cord blood bank.

(2) The number of postnatal donations used for transplants and the number of postnatal donations used for research.

Chapter 2. Umbilical Cord Blood Donation Initiative

Sec. 1. As used in this chapter, "initiative" refers to the umbilical cord blood donation initiative established under section 2 of this chapter.

Sec. 2. The nonprofit corporation shall establish an umbilical cord blood donation initiative to promote public awareness concerning the following:

(1) A pregnant woman's option to make a postnatal donation upon the birth of a newborn infant.

(2) The medical benefits of postnatal tissue and postnatal fluids.

(3) The importance of donating umbilical cord blood to the public umbilical cord blood bank.

Sec. 3. The nonprofit corporation may accept a grant from the federal government, money from the state government, and private contributions to establish and implement the initiative.

Sec. 4. (a) The initiative must include the dissemination of written material that includes the following:

(1) Information concerning the option that is available to a pregnant woman to make a postnatal donation upon the birth of a newborn infant.

(2) An explanation of the benefits of public umbilical cord blood banking.

(3) The benefits of umbilical cord blood in accordance with the National Marrow Donor Program or another federal Food and Drug Administration approved protocol and the use of umbilical cord blood for medical treatment, including the following:

(A) A list of the diseases or conditions that have been treated through the use of umbilical cord blood.

(B) A list of the diseases or conditions for which scientific research indicates that treatment through the use of umbilical cord blood is promising.

(4) Information on the public umbilical cord blood bank.

(5) Information concerning the process by which postnatal tissue and postnatal fluid are collected and the steps that a pregnant woman must take before her child is born to arrange to have the postnatal tissue and postnatal fluid collected and donated.

(b) The nonprofit corporation shall:

(1) update the material described in subsection (a); and

(2) distribute the material to the following persons that treat pregnant women:

(A) Physicians licensed under IC 25-22.5.

(B) Participating hospitals.

(C) Ambulatory surgical centers.

(D) Health clinics.

(E) Maternity homes registered under IC 16-26-1.

(F) Nurse midwives licensed under IC 25-23-1-13.1.

Sec. 5. The nonprofit corporation shall develop a process for physicians, nurse midwives, birthing centers, and participating hospitals to inform eligible candidates of the opportunity to make postnatal donations to the public umbilical cord blood bank following delivery of a newborn infant.

Sec. 6. The nonprofit corporation that establishes the initiative described in this chapter must meet all the requirements and responsibilities set forth in IC 23-17.

Sec. 7. (a) Any intellectual property developed by the nonprofit corporation establishing the initiative under this chapter is the property of the nonprofit corporation. A donor must consent to release to the public umbilical cord blood bank any property right related to the postnatal donation, including any claim of intellectual property rights derived from the postnatal donation.

(b) The entire right, title, and interest in and to any intellectual property derived from a postnatal donation transfers with the postnatal tissue and postnatal fluid after the postnatal donation is allocated by the public umbilical cord blood bank for research purposes.

SECTION 17. IC 16-18-2-36.5, AS ADDED BY P.L.96-2005, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 36.5. (a) "Birthing center", for purposes of IC 16-21-2 **and IC 16-21-7.5,** means a freestanding entity that has the sole purpose of delivering a normal or uncomplicated pregnancy.

(b) The term does not include a hospital that is licensed as a hospital under IC 16-21-2.

SECTION 18. IC 16-21-7.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]:

Chapter 7.5. Hospital and Birthing Center Requirement Regarding Umbilical Cord Blood Donation

Sec. 1. As used in this chapter, "postnatal donation" has the meaning set forth in IC 12-31-1-2.

Sec. 2. Before a hospital or birthing center participates in collecting donations for the public umbilical cord blood bank established under IC 12-31-1-3(a), the hospital or birthing center shall enter into a written agreement with the public umbilical cord blood bank establishing the:

(1) conditions of the hospital's or birthing center's participation; and

(2) obligations of the hospital or birthing center;

in the umbilical cord blood donation initiative established under IC 12-31-2-2.

Sec. 3. (a) Except as provided in section 4 of this chapter, a participating hospital or birthing center licensed under this article must offer a patient who delivers a newborn infant at the participating hospital or birthing center the option of making a postnatal donation following delivery of the newborn infant.

(b) A patient may not be charged for the collection, storage, or donation to the public umbilical cord blood bank established under IC 12-31-1-3(a).

Sec. 4. (a) A participating hospital or birthing center is not required to collect a postnatal donation if either of the following applies:

(1) In the professional judgment of a physician licensed under IC 25-22.5 or a nurse midwife licensed under IC 25-23-1-13.1,

the collection would threaten the health of the mother or the infant.

(2) The postnatal donation is contrary to the moral principles or beliefs of the religious denomination with which the participating hospital or birthing center is affiliated.

(b) An employee of a participating hospital or birthing center is not required to collect a postnatal donation if the postnatal donation is contrary to the religious principles or beliefs of the employee.

Sec. 5. A participating hospital or birthing center shall cooperate with the nonprofit corporation (as defined in IC 12-31-1-1) in accomplishing the public health goal of maximizing postnatal donations.

Sec. 6. A hospital or birthing center is not required to enter into an agreement with the public umbilical cord blood bank and may enter into contracts concerning postnatal tissue and postnatal fluids with any person.

SECTION 19. IC 12-23-18-6 IS REPEALED [EFFECTIVE JULY 1, 2008].

SECTION 20. [EFFECTIVE JULY 1, 2008] **(a) The office of the secretary of family and social services shall adopt the rules required by IC 12-31-1-3(b), as added by this act, in the manner provided in IC 4-22-2-37.1. The office shall immediately begin the adoption of the rules and shall adopt the final rules before March 1, 2009.**

(b) This SECTION expires July 1, 2009.

SENATE MOTION

Madam President: I move that Senator Sipes be added as second author of Senate Bill 157.

MILLER

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 157, 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 1, line 6, delete "C.F.R." and insert "**CFR Part**".

Page 1, delete lines 8 through 17.

Page 2, line 5, after "program" insert "**is specifically approved and the opiate treatment facility**".

Page 2, delete lines 6 through 7.

Page 2, line 9, delete "(3)" and insert "**(2)**".

Page 2, line 11, after "Separate" insert " **specific approval and**".

Page 3, line 10, strike "of:" and insert "**that is:**".

Page 3, line 11, strike "twenty dollars ($20) for each".

Page 3, line 11, delete "resident; and".

Page 3, line 12, delete "(2) three hundred dollars ($300) for each".

Page 3, line 12, strike "nonresident;".

Page 3, line 13, delete "of Indiana" and insert "**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.".

Page 3, run in lines 11 through 13.

Page 3, line 20, strike "diversion".

Page 3, line 21, strike "control and oversight".

Page 3, line 22, strike "diversion control and".

Page 3, line 23, strike "oversight".

Page 4, between lines 5 and 6, begin a new line double block indented and insert:

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

Page 4, line 6, after "(2)" insert "**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)".

Page 4, line 7, delete "chapter." and insert "**chapter as described in section 3 of this chapter.**".

Page 4, line 38, after "IC 5-14-6" insert "**, the state department of health,**".

Page 5, delete lines 8 through 11.

Page 5, line 12, delete "(7)" and insert "**(5)**".

Page 5, line 12, delete "rehabilitated" and insert "**determined to be no longer in need of services**".

Page 5, line 14, delete "(8)" and insert "**(6)**".

Page 5, line 16, delete "(9)" and insert "**(7)**".

Page 5, between lines 17 and 18, begin a new line single block indented and insert:

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

Page 5, line 23, after "program's" insert "**specific approval to operate as an opioid treatment program or the opioid treatment facility's**".

Page 5, delete lines 29 through 42, begin a new paragraph and insert:

"SECTION 11. IC 12-23-18-5.8 IS ADDED TO THE INDIANA 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 the 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 the 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.".

Delete pages 6 through 8.

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 157 as introduced.)

MILLER, Chairperson

Committee Vote: Yeas 11, Nays 0.

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred Senate Bill 157, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 1, between the enacting clause and line 1, begin a new paragraph and insert:

"SECTION 1. IC 12-7-2-118.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: **Sec. 118.3. "Initiative", for purposes of IC 12-31-2, has the meaning set forth in IC 12-31-2-1.**

SECTION 2. IC 12-7-2-132.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: **Sec. 132.5. "Nonprofit corporation", for purposes of IC 12-31, has the meaning set forth in IC 12-31-1-1.**".

Page 1, between lines 7 and 8, begin a new paragraph and insert:

"SECTION 4. IC 12-7-2-142.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: **Sec. 142.7. "Postnatal donation", for purposes of IC 12-31, has the meaning set forth in IC 12-31-1-2.**".

Page 2, line 31, after "that" insert "**: (1)**".

Page 2, line 32, delete "." and insert "; **and**".

Page 2, between lines 32 and 33, begin a new line block indented and insert:

"**(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.**".

Page 2, between lines 37 and 38, begin a new paragraph and insert:

"SECTION 9. 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 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 drug that has been determined to be abused in the program's locality or any other 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 must administer an administrative medical detoxification program not to exceed fourteen (14) days.".

Page 3, line 5, after "patient" delete ".".

Page 3, after line 42, begin a new line double block indented and insert:

"**(E) A statement to be used by opioid treatment facilities that:**

(i) acknowledges that the patient will be driven from the facility by another responsible person after receiving opioid treatment medications; and

(ii) is signed by the patient and person who will drive the patient at the time the patient arrives to receive opioid treatment medications.".

Page 6, between lines 10 and 11, begin a new paragraph and insert:

"SECTION 16. IC 12-31 IS ADDED TO THE INDIANA CODE AS A **NEW** ARTICLE TO READ AS FOLLOWS [EFFECTIVE JULY 1,

2008]:

ARTICLE 31. UMBILICAL CORD BLOOD

Chapter 1. Public Umbilical Cord Blood Bank

Sec. 1. As used in this article, "nonprofit corporation" refers to the Indiana nonprofit corporation formed by the office of the secretary under section 3 of this chapter to establish and operate a public umbilical cord blood bank.

Sec. 2. As used in this article, "postnatal donation" means any of the following donations by a patient to the public umbilical cord blood bank:

(1) Postnatal fluid, including umbilical cord blood.

(2) Postnatal tissue, including the placenta and tissue extracted from an umbilical cord.

Sec. 3. (a) The office of the secretary shall form a nonprofit corporation to establish and provide for the operation of a public umbilical cord blood bank to promote public health and to exercise other essential governmental functions.

(b) The office of the secretary shall adopt rules under IC 4-22-2 concerning the protection of individual identifiable health information regarding the operation of the public umbilical cord blood bank.

Sec. 4. (a) The board of directors of the nonprofit corporation consists of the following:

(1) The state health commissioner or the commissioner's designee.

(2) The secretary or the secretary's designee.

(3) The secretary of commerce appointed under IC 5-28-3-4 or the secretary's designee.

(4) The director of the state department of health's office of minority health.

(5) The following individuals appointed by the governor:

(A) One (1) president or chief executive officer of an Indiana based hospital.

(B) One (1) research scientist with expertise in umbilical cord blood research.

(C) One (1) ethicist with expertise in bioethics.

(D) One (1) physician licensed under IC 25-22.5 who specializes in birthing and delivery.

(E) One (1) representative of a donor umbilical cord blood bank facility.

(F) One (1) member of the interagency state council on black and minority health established under IC 16-46-6.

(b) The board of directors shall appoint an advisory board. At least fifty-one percent (51%) of the advisory board members must be research scientists with expertise in stem cell research.

(c) The advisory board, using criteria established by the board of directors, is responsible for reviewing applications from research scientists, research institutions, and other persons interested in receiving a postnatal donation that is ineligible for transplant use from the public umbilical cord blood bank.

(d) The board of directors may contract with a person to perform the management and administrative operations of the public umbilical cord blood bank. The person shall follow the federal Food and Drug Administration's current good tissue practices.

(e) Subject to approval by the budget agency, the board of directors may, without the approval of the attorney general, employ legal counsel, technical experts, and other officers, agents, and employees that the board of directors considers necessary to carry out the efficient operation of a public umbilical cord blood bank.

(f) The board of directors shall determine the terms and conditions of the participating agreement that is executed with each participating hospital.

Sec. 5. The nonprofit corporation shall do the following:

(1) Establish procedures and guidelines for collecting, maintaining, and receiving postnatal donations.

(2) Educate health care professionals about the procedures and requirements for collecting and maintaining postnatal donations following the birth of a newborn infant.

(3) Establish procedures concerning patient informed consent and privacy that are approved by an independent institutional review board selected by the board of directors.

Sec. 6. (a) The nonprofit corporation shall accept postnatal donations at no charge or cost to the donor.

(b) The nonprofit corporation may allow the following to use the postnatal donations:

(1) Transplant centers.

(2) Research centers approved by the nonprofit corporation that will use the postnatal donation to promote medical advances, life science research, or biotechnology research.

(3) Any other entity approved by the nonprofit corporation if the entity will use the postnatal donation to promote medical advances, life science research, or biotechnology research.

(c) Any postnatal donations maintained by the public umbilical cord blood bank must be allocated as follows:

(1) Postnatal donations that are of transplantable quality according to the National Marrow Donor Program, the federal Food and Drug Administration's approved protocol, or other relevant national practice and quality standards must be allocated for medical transplants.

(2) Postnatal donations that do not meet the transplant quality standards referred to in subdivision (1) and that are suitable for research must be made available for scientific research or medical treatments that comply with relevant national practice and quality standards.

(d) The nonprofit corporation shall acquire and maintain adequate liability insurance coverage.

Sec. 7. The nonprofit corporation may maintain postnatal donations at no charge or cost to the donor.

Sec. 8. The nonprofit corporation may award a grant to a person for work with postnatal donations.

Sec. 9. The nonprofit corporation shall report annually to the health finance commission established by IC 2-5-23-3 concerning the following:

(1) The implementation of the umbilical cord blood bank.

(2) The number of postnatal donations used for transplants and the number of postnatal donations used for research.

Chapter 2. Umbilical Cord Blood Donation Initiative

Sec. 1. As used in this chapter, "initiative" refers to the umbilical cord blood donation initiative established under section 2 of this chapter.

Sec. 2. The nonprofit corporation shall establish an umbilical cord blood donation initiative to promote public awareness concerning the following:

(1) A pregnant woman's option to make a postnatal donation upon the birth of a newborn infant.

(2) The medical benefits of postnatal tissue and postnatal fluids.

(3) The importance of donating umbilical cord blood to the public umbilical cord blood bank.

Sec. 3. The nonprofit corporation may accept a grant from the federal government, money from the state government, and private contributions to establish and implement the initiative.

Sec. 4. (a) The initiative must include the dissemination of written material that includes the following:

(1) Information concerning the option that is available to a pregnant woman to make a postnatal donation upon the birth of a newborn infant.

(2) An explanation of the benefits of public umbilical cord blood banking.

(3) The benefits of umbilical cord blood in accordance with the National Marrow Donor Program or another federal Food and Drug Administration approved protocol and the use of umbilical cord blood for medical treatment, including the following:

(A) A list of the diseases or conditions that have been treated through the use of umbilical cord blood.

(B) A list of the diseases or conditions for which scientific research indicates that treatment through the use of umbilical cord blood is promising.

(4) Information on the public umbilical cord blood bank.

(5) Information concerning the process by which postnatal tissue and postnatal fluid are collected and the steps that a pregnant woman must take before her child is born to arrange to have the postnatal tissue and postnatal fluid collected and donated.

(b) The nonprofit corporation shall:

(1) update the material described in subsection (a); and

(2) distribute the material to the following persons that treat pregnant women:

(A) Physicians licensed under IC 25-22.5.

(B) Participating hospitals.

(C) Ambulatory surgical centers.

(D) Health clinics.

(E) Maternity homes registered under IC 16-26-1.

(F) Nurse midwives licensed under IC 25-23-1-13.1.

Sec. 5. The nonprofit corporation shall develop a process for physicians, nurse midwives, birthing centers, and participating hospitals to inform eligible candidates of the opportunity to make postnatal donations to the public umbilical cord blood bank following delivery of a newborn infant.

Sec. 6. The nonprofit corporation that establishes the initiative described in this chapter must meet all the requirements and responsibilities set forth in IC 23-17.

Sec. 7. (a) Any intellectual property developed by the nonprofit corporation establishing the initiative under this chapter is the property of the nonprofit corporation. A donor must consent to

release to the public umbilical cord blood bank any property right related to the postnatal donation, including any claim of intellectual property rights derived from the postnatal donation.

(b) The entire right, title, and interest in and to any intellectual property derived from a postnatal donation transfers with the postnatal tissue and postnatal fluid after the postnatal donation is allocated by the public umbilical cord blood bank for research purposes.

SECTION 21. IC 16-18-2-36.5, AS ADDED BY P.L.96-2005, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 36.5. (a) "Birthing center", for purposes of IC 16-21-2 **and IC 16-21-7.5,** means a freestanding entity that has the sole purpose of delivering a normal or uncomplicated pregnancy.

(b) The term does not include a hospital that is licensed as a hospital under IC 16-21-2.

SECTION 22. IC 16-21-7.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]:

Chapter 7.5. Hospital and Birthing Center Requirement Regarding Umbilical Cord Blood Donation

Sec. 1. As used in this chapter, "postnatal donation" has the meaning set forth in IC 12-31-1-2.

Sec. 2. Before a hospital or birthing center participates in collecting donations for the public umbilical cord blood bank established under IC 12-31-1-3(a), the hospital or birthing center shall enter into a written agreement with the public umbilical cord blood bank establishing the:

(1) conditions of the hospital's or birthing center's participation; and

(2) obligations of the hospital or birthing center;

in the umbilical cord blood donation initiative established under IC 12-31-2-2.

Sec. 3. (a) Except as provided in section 4 of this chapter, a participating hospital or birthing center licensed under this article must offer a patient who delivers a newborn infant at the participating hospital or birthing center the option of making a postnatal donation following delivery of the newborn infant.

(b) A patient may not be charged for the collection, storage, or donation to the public umbilical cord blood bank established under IC 12-31-1-3(a).

Sec. 4. (a) A participating hospital or birthing center is not required to collect a postnatal donation if either of the following

applies:

(1) In the professional judgment of a physician licensed under IC 25-22.5 or a nurse midwife licensed under IC 25-23-1-13.1, the collection would threaten the health of the mother or the infant.

(2) The postnatal donation is contrary to the moral principles or beliefs of the religious denomination with which the participating hospital or birthing center is affiliated.

(b) An employee of a participating hospital or birthing center is not required to collect a postnatal donation if the postnatal donation is contrary to the religious principles or beliefs of the employee.

Sec. 5. A participating hospital or birthing center shall cooperate with the nonprofit corporation (as defined in IC 12-31-1-1) in accomplishing the public health goal of maximizing postnatal donations.

Sec. 6. A hospital or birthing center is not required to enter into an agreement with the public umbilical cord blood bank and may enter into contracts concerning postnatal tissue and postnatal fluids with any person.".

Page 6, after line 12, begin a new paragraph and insert:

"SECTION 27. [EFFECTIVE JULY 1, 2008] **(a) The office of the secretary of family and social services shall adopt the rules required by IC 12-31-1-3(b), as added by this act, in the manner provided in IC 4-22-2-37.1. The office shall immediately begin the adoption of the rules and shall adopt the final rules before March 1, 2009.**

(b) This SECTION expires July 1, 2009.".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 157 as printed January 25, 2008.)

BROWN C, Chair

Committee Vote: yeas 11, nays 0.

HOUSE MOTION

Mr. Speaker: I move that Engrossed Senate Bill 157 be amended to read as follows:

Page 3, line 16, after "test" insert "**, including before receiving treatment,**".

Page 3, line 25, delete "other drug that has been determined to be abused in".

Page 3, line 25, delete "the program's locality or any".

Page 3, line 26, after "other" insert "**suspected or known**".

Page 3, line 35, delete "must administer an administrative" and insert "**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 from 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).

(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.".

Page 3, delete line 36.

Page 4, delete line 42.

Page 5, delete lines 1 through 7.

Page 6, between lines 23 and 24, begin a new line block indented and insert:

"**(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.**".

(Reference is to ESB 157 as printed February 22, 2008.)

STEMLER