



April 8, 2013

**ENGROSSED  
SENATE BILL No. 272**

DIGEST OF SB 272 (Updated April 8, 2013 12:29 pm - DI 77)

**Citations Affected:** IC 16-18; IC 16-42; noncode.

**Synopsis:** Prescription products. Allows a pharmacist to substitute an interchangeable biosimilar product for a prescribed biological product if certain conditions are met. Requires the board of pharmacy to maintain an Internet web site that lists the biosimilar biological products that are determined to be interchangeable. Allows the board of pharmacy to adopt rules. Provides that a written or electronic prescription for a biological product must comply with the existing prescription form requirements. Requires, during the 2013 legislative interim: (1) the division of mental health and addiction to provide the health finance commission with specified information concerning opioid treatment programs; and (2) the health finance commission to study how Indiana law should address the prescribing and substituting of biosimilar biological products.

**Effective:** July 1, 2013; July 1, 2014.

**Miller Patricia, Grooms, Breaux**

(HOUSE SPONSOR — DAVISSON)

January 8, 2013, read first time and referred to Committee on Health and Provider Services.

February 7, 2013, amended, reported favorably — Do Pass.

February 12, 2013, read second time, amended, ordered engrossed.

February 13, 2013, engrossed.

February 14, 2013, returned to second reading.

February 21, 2013, re-read second time, amended, ordered engrossed.

February 22, 2013, re-engrossed.

February 25, 2013, read third time, passed. Yeas 50, nays 0.

**HOUSE ACTION**

March 4, 2013, read first time and referred to Committee on Public Health.

April 8, 2013, amended, reported — Do Pass.

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ES 272—LS 6848/DI 104+



April 8, 2013

First Regular Session 118th General Assembly (2013)

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 2012 Regular Session of the General Assembly.

## ENGROSSED SENATE BILL No. 272

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 16-18-2-35.8 IS ADDED TO THE INDIANA  
2 CODE AS A **NEW** SECTION TO READ AS FOLLOWS  
3 [EFFECTIVE JULY 1, 2013]: **Sec. 35.8. "Biological product", for**  
4 **purposes of IC 16-42-25, has the meaning set forth in**  
5 **IC 16-42-25-1.**

6 SECTION 2. IC 16-18-2-36.2 IS ADDED TO THE INDIANA  
7 CODE AS A **NEW** SECTION TO READ AS FOLLOWS  
8 [EFFECTIVE JULY 1, 2013]: **Sec. 36.2. "Biosimilar", for purposes**  
9 **of IC 16-42-25, has the meaning set forth in IC 16-42-25-2.**

10 SECTION 3. IC 16-18-2-191.2 IS ADDED TO THE INDIANA  
11 CODE AS A **NEW** SECTION TO READ AS FOLLOWS  
12 [EFFECTIVE JULY 1, 2013]: **Sec. 191.2. "Interchangeable", for**  
13 **purposes of IC 16-42-25, has the meaning set forth in**  
14 **IC 16-42-25-3.**

15 SECTION 4. IC 16-18-2-288 IS AMENDED TO READ AS  
16 FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 288. (a) "Practitioner",**  
17 **for purposes of IC 16-42-19, has the meaning set forth in**

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1 IC 16-42-19-5.

2 (b) "Practitioner", for purposes of IC 16-41-14, has the meaning set  
3 forth in IC 16-41-14-4.

4 (c) "Practitioner", for purposes of IC 16-42-21, has the meaning set  
5 forth in IC 16-42-21-3.

6 (d) "Practitioner", for purposes of IC 16-42-22 **and IC 16-42-25**,  
7 has the meaning set forth in IC 16-42-22-4.5.

8 SECTION 5. IC 16-18-2-313.5 IS ADDED TO THE INDIANA  
9 CODE AS A **NEW SECTION TO READ AS FOLLOWS**  
10 [EFFECTIVE JULY 1, 2013]: **Sec. 313.5. "Reference product", for**  
11 **purposes of IC 16-42-25, has the meaning set forth in**  
12 **IC 16-42-25-4.**

13 SECTION 6. IC 16-42-22-8, AS AMENDED BY P.L.204-2005,  
14 SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE  
15 JULY 1, 2013]: Sec. 8. (a) For substitution to occur for a prescription  
16 other than a prescription filled under the Medicaid program (42 U.S.C.  
17 1396 et seq.), the children's health insurance program established under  
18 IC 12-17.6-2, **the biosimilar biological products requirements under**  
19 **IC 16-42-25**, or the Medicare program (42 U.S.C. 1395 et seq.):

20 (1) the practitioner must:

21 (A) sign on the line under which the words "May substitute"  
22 appear; or

23 (B) for an electronically transmitted prescription,  
24 electronically transmit the instruction "May substitute."; and

25 (2) the pharmacist must inform the customer of the substitution.

26 (b) This section does not authorize any substitution other than  
27 substitution of a generically equivalent drug product.

28 SECTION 7. IC 16-42-25 IS ADDED TO THE INDIANA CODE  
29 AS A **NEW CHAPTER TO READ AS FOLLOWS** [EFFECTIVE  
30 JULY 1, 2014]:

31 **Chapter 25. Drugs: Biosimilar Biological Products**

32 **Sec. 1. As used in this chapter, "biological product" means:**

33 (1) a virus;

34 (2) a therapeutic serum;

35 (3) a toxin;

36 (4) an antitoxin;

37 (5) a vaccine;

38 (6) blood;

39 (7) a blood component;

40 (8) a blood derivative;

41 (9) an allergenic product;

42 (10) a protein (except any chemically synthesized

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1 polypeptide);

2 (11) a product analogous to a product described in  
3 subdivisions (1) through (10);

4 (12) arsphenamine;

5 (13) an arsphenamine derivative; or

6 (14) any other trivalent organic arsenic compound;

7 applicable to the prevention, treatment, or cure of a disease or  
8 condition for human beings.

9 Sec. 2. As used in this chapter, "biosimilar" means a biological  
10 product that:

11 (1) has been licensed as a biosimilar product under 42 U.S.C.  
12 262(k); and

13 (2) is highly similar to the reference product, with:

14 (A) no clinically meaningful differences between the  
15 biological product and the reference product in terms of  
16 safety, purity, and potency of the product; and

17 (B) only minor differences in clinically inactive  
18 components.

19 Sec. 3. As used in this chapter, "interchangeable" means a  
20 determination by the federal Food and Drug Administration that  
21 a biosimilar product may be substituted for a reference product  
22 without the intervention of the health care provider that prescribed  
23 the biological product.

24 Sec. 4. As used in this chapter, "reference product" means the  
25 single biological product licensed under 42 U.S.C. 262(a) against  
26 which a biological product is evaluated in an application submitted  
27 under 42 U.S.C. 262(k).

28 Sec. 5. A pharmacist may substitute a biosimilar product for a  
29 prescribed biological product if the following conditions are met:

30 (1) The biosimilar product has been determined by the federal  
31 Food and Drug Administration to be interchangeable with the  
32 prescribed biological product.

33 (2) The prescribing practitioner has:

34 (A) for a written prescription, signed on the line under  
35 which the words "May substitute." appear; or

36 (B) for an electronically transmitted prescription,  
37 electronically transmitted the instruction "May  
38 substitute.".

39 (3) The pharmacist has informed the customer of the  
40 substitution.

41 (4) The pharmacist notifies the prescribing practitioner,  
42 orally, in writing, or electronically, within five (5) calendar

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days of the substitution.

(5) The pharmacy and the prescribing practitioner retain a written or electronic record of the interchangeable biosimilar substitution for at least five (5) years.

Sec. 6. (a) The Indiana board of pharmacy shall maintain a public Internet web site that contains a current list of biosimilar biological products that the federal Food and Drug Administration has determined to be interchangeable.

(b) The Indiana board of pharmacy may adopt rules under IC 4-22-2 necessary to implement this chapter.

Sec. 7. A written or electronic prescription for a biological product must comply with the requirements under IC 16-42-22-6.

SECTION 8. [EFFECTIVE JULY 1, 2013] (a) As used in this SECTION, "commission" refers to the health finance commission established by IC 2-5-23-3.

(b) During the 2013 legislative interim, the commission shall study the following:

(1) The expansion of the INSPECT (as defined by IC 35-48-7-5.2) program, including:

(A) requiring real time reporting of collected information;

(B) studying the confidentiality issues concerning access to the INSPECT database;

(C) requiring health care practitioners who prescribe medications to report all legend drugs and the proper time frame to require the reporting; and

(D) having health care providers access information in the INSPECT database that would assist the health care practitioner in the treatment of patients.

(2) The use of methadone and opioids in treatment programs and clinic settings.

(c) Not later than September 1, 2013, the division of mental health and addiction shall provide the commission with the following information in writing:

(1) The number of patients served in Indiana opioid treatment programs certified under IC 12-23-18.

(2) The opioid treatment medications provided to patients, including the dosage.

(3) The drug testing protocol of Indiana opioid treatment programs.

(4) The number of opioid treatment program patients who have tested positive for other controlled substances during a drug test for a controlled substance provided under an opioid

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**treatment program.**

**(5) The number of opioid treatment program patients who are subsequently determined to no longer need the assistance of the opioid treatment program and released from treatment.**

**(6) Any other information requested by the commission or that is determined by the division of mental health and addiction to be relevant to the study described in this SECTION.**

**(d) During the 2013 legislative interim, the commission shall study how Indiana law should address the prescribing and substituting of biosimilar biological products for other drugs.**

**(e) This SECTION expires December 31, 2013.**

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## COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 272, 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, delete lines 14 through 42.

Delete page 3.

Page 4, delete lines 1 through 4.

Page 5, after line 8, begin a new paragraph and insert:

"SECTION 5. IC 35-48-7-2.9, AS ADDED BY P.L.105-2008, SECTION 65, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 2.9. (a) As used in this chapter, "dispense" has the meaning set forth in IC 35-48-1-12.

(b) The term does not apply to the following:

(1) A drug administered directly to a patient.

(2) A drug dispensed by a practitioner, if the quantity dispensed is not more than:

(A) a seventy-two (72) hour supply of a controlled substance listed in schedule II, III, IV, or V as set forth in IC 35-48-3-9;

or

**(B) beginning January 1, 2014, a ten (10) day supply of a prescription drug that is not described in clause (A) and that is provided at no cost to the patient.**

SECTION 6. IC 35-48-7-5.4, AS ADDED BY P.L.65-2006, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 5.4. As used in this chapter, "interoperability" refers to the INSPECT program electronically sharing reported information with another state concerning the dispensing of a controlled substance, **or beginning January 1, 2014, a prescription drug:**

(1) to a recipient who resides in the other state; or

(2) prescribed by a practitioner whose principal place of business is located in another state.

SECTION 7. IC 35-48-7-5.8, AS ADDED BY P.L.65-2006, SECTION 6, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 5.8. As used in this chapter, "practitioner" means a physician, dentist, veterinarian, podiatrist, nurse practitioner, scientific investigator, pharmacist, hospital, or other institution or individual licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled

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substance **or, beginning January 1, 2014, a prescription drug** in the course of professional practice or research in the United States.

SECTION 8. IC 35-48-7-6 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 6. As used in this chapter, "recipient" means an individual for whom a controlled substance **or, beginning January 1, 2014, a prescription drug** is dispensed.

SECTION 9. IC 35-48-7-7 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 7. As used in this chapter, "recipient representative" means the individual to whom a controlled substance **or, beginning January 1, 2014, a prescription drug** is dispensed if the recipient is either less than eighteen (18) years of age or unavailable to receive the controlled substance **or prescription drug**.

SECTION 10. IC 35-48-7-8.1, AS AMENDED BY P.L.152-2012, SECTION 14, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 8.1. (a) The board shall provide for a controlled substance **prescription monitoring program or, beginning January 1, 2014, a prescription drug** monitoring program that includes the following components:

(1) Each time a controlled substance designated by the board under IC 35-48-2-5 through IC 35-48-2-10 **or, beginning January 1, 2014, a prescription drug** is dispensed, the dispenser shall transmit to the INSPECT program the following information:

- (A) The controlled substance **or prescription drug** recipient's name.
- (B) The controlled substance **or prescription drug** recipient's or the recipient representative's identification number or the identification number or phrase designated by the INSPECT program.
- (C) The controlled substance **or prescription drug** recipient's date of birth.
- (D) The national drug code number of the controlled substance **or prescription drug** dispensed.
- (E) The date the controlled substance **or prescription drug** is dispensed.
- (F) The quantity of the controlled substance **or prescription drug** dispensed.
- (G) The number of days of supply dispensed.
- (H) **If the drug is a controlled substance**, the dispenser's United States Drug Enforcement Agency registration number.



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(I) **If the drug is a controlled substance**, the prescriber's United States Drug Enforcement Agency registration number.

(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

(K) Other data required by the board.

(2) The information required to be transmitted under this section must be transmitted not more than seven (7) days after the date on which a controlled substance **or, beginning January 1, 2014, a prescription drug** is dispensed.

(3) A dispenser shall transmit the information required under this section by:

(A) uploading to the INSPECT web site;

(B) a computer diskette; or

(C) a CD-ROM disk;

that meets specifications prescribed by the board.

(4) The board may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the board may not apply such a requirement to prescriptions filled at a pharmacy with a Category II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The board may not require multiple copy prescription forms for any prescriptions written. The board may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be approved by the Indiana board of pharmacy established by IC 25-26-13-3.

(5) The costs of the program.

(b) This subsection applies only to a retail pharmacy. A pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance may not dispense a controlled substance to a person who is not personally known to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance unless the person taking possession of the controlled substance provides documented proof of the person's identification to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance.

SECTION 11. IC 35-48-7-10.1, AS AMENDED BY P.L.84-2010, SECTION 98, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 10.1. (a) The INSPECT program must do the following:

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(1) Create a data base for information required to be transmitted under section 8.1 of this chapter in the form required under rules adopted by the board, including search capability for the following:

(A) A controlled substance **or prescription drug** recipient's name.

(B) A controlled substance **or prescription drug** recipient's or recipient representative's identification number.

(C) A controlled substance **or prescription drug** recipient's date of birth.

(D) The national drug code number of a controlled substance **or prescription drug** dispensed.

(E) The dates a controlled substance **or prescription drug** is dispensed.

(F) The quantities of a controlled substance **or prescription drug** dispensed.

(G) The number of days of supply dispensed.

(H) A dispenser's United States Drug Enforcement Agency registration number.

(I) A prescriber's United States Drug Enforcement Agency registration number.

(J) Whether a prescription was transmitted to the pharmacist orally or in writing.

(K) A controlled substance **or prescription drug** recipient's method of payment for the controlled substance **or prescription drug** dispensed.

(2) Provide the board with continuing twenty-four (24) hour a day online access to the data base.

(3) Secure the information collected and the data base maintained against access by unauthorized persons.

(b) The board may execute a contract with a vendor designated by the board to perform any function associated with the administration of the INSPECT program.

(c) The INSPECT program may gather prescription data from the Medicaid retrospective drug utilization review (DUR) program established under IC 12-15-35.

(d) The board may accept and designate grants, public and private financial assistance, and licensure fees to provide funding for the INSPECT program.

SECTION 12. IC 35-48-7-11.1, AS AMENDED BY P.L.84-2010, SECTION 99, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 11.1. (a) Information received by the INSPECT

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program under section 8.1 of this chapter is confidential.

(b) The board shall carry out a program to protect the confidentiality of the information described in subsection (a). The board may disclose the information to another person only under subsection (c), (d), or (g).

(c) The board may disclose confidential information described in subsection (a) to any person who is authorized to engage in receiving, processing, or storing the information.

(d) Except as provided in subsections (e) and (f), the board may release confidential information described in subsection (a) to the following persons:

(1) A member of the board or another governing body that licenses practitioners and is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance.

(2) An investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general, who is engaged in:

- (A) an investigation;
- (B) an adjudication; or
- (C) a prosecution;

of a violation under any state or federal law that involves a controlled substance.

(3) A law enforcement officer who is an employee of:

- (A) a local, state, or federal law enforcement agency; or
- (B) an entity that regulates controlled substances or enforces controlled substances rules or laws in another state;

that is certified to receive information from the INSPECT program **as described in subsection (e)(1)**.

(4) A practitioner or practitioner's agent certified to receive information from the INSPECT program.

(5) A **prescription drug or** controlled substance monitoring program in another state with which Indiana has established an interoperability agreement.

(6) The state toxicologist.

(7) A certified representative of the Medicaid retrospective and prospective drug utilization review program.

(8) A substance abuse assistance program for a licensed health care provider who:

- (A) has prescriptive authority under IC 25; and
- (B) is participating in the assistance program.

(e) Information provided to an individual under:

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(1) subsection (d)(3) is limited to **controlled substances** information:

(A) concerning an individual or proceeding involving the unlawful diversion or misuse of a schedule II, III, IV, or V controlled substance; and

(B) that will assist in an investigation or proceeding; and

(2) subsection (d)(4) may be released only for the purpose of:

(A) providing medical or pharmaceutical treatment; or

(B) evaluating the need for providing medical or pharmaceutical treatment to a patient.

(f) Before the board releases confidential information under subsection (d), the applicant must be approved by the INSPECT program in a manner prescribed by the board.

(g) The board may release to:

(1) a member of the board or another governing body that licenses practitioners;

(2) an investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general; or

(3) a law enforcement officer who is:

(A) authorized by the state police department to receive the type of information released; and

(B) approved by the board to receive the type of information released;

confidential information generated from computer records that identifies practitioners who are prescribing or dispensing large quantities of a controlled substance.

(h) The information described in subsection (g) may not be released until it has been reviewed by:

(1) a member of the board who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data;

or

(2) the board's designee;

and until that member or the designee has certified that further investigation is warranted. However, failure to comply with this subsection does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (i).

(i) An investigator or a law enforcement officer receiving confidential information under subsection (c), (d), or (g) may disclose the information to a law enforcement officer or an attorney for the office of the attorney general for use as evidence in the following:

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- (1) A proceeding under IC 16-42-20.
- (2) A proceeding under any state or federal law that involves a controlled substance.
- (3) A criminal proceeding or a proceeding in juvenile court that involves a controlled substance.

(j) The board may compile statistical reports from the information described in subsection (a). The reports must not include information that identifies any practitioner, ultimate user, or other person administering a controlled substance **or a prescription drug**. Statistical reports compiled under this subsection are public records.

(k) This section may not be construed to require a practitioner to obtain information about a patient from the data base.

(l) A practitioner is immune from civil liability for an injury, death, or loss to a person solely due to a practitioner seeking or not seeking information from the INSPECT program. The civil immunity described in this subsection does not extend to a practitioner if the practitioner receives information directly from the INSPECT program and then negligently misuses this information. This subsection does not apply to an act or omission that is a result of gross negligence or intentional misconduct.

(m) The board may review the records of the INSPECT program. If the board determines that a violation of the law may have occurred, the board shall notify the appropriate law enforcement agency or the relevant government body responsible for the licensure, regulation, or discipline of practitioners authorized by law to prescribe ~~controlled substances~~ **prescription drugs**.

(n) A practitioner who in good faith discloses information based on a report from the INSPECT program to a law enforcement agency is immune from criminal or civil liability. A practitioner that discloses information to a law enforcement agency under this subsection is presumed to have acted in good faith.

SECTION 13. IC 35-48-7-12.1, AS AMENDED BY P.L.42-2011, SECTION 77, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 12.1. (a) The board shall adopt rules under IC 4-22-2 to implement this chapter, including the following:

- (1) Information collection and retrieval procedures for the INSPECT program, including the controlled substances **or beginning January 1, 2014, prescription drugs**, to be included in the program required under section 8.1 of this chapter.
- (2) Design for the creation of the data base required under section 10.1 of this chapter.
- (3) Requirements for the development and installation of online



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electronic access by the board to information collected by the INSPECT program.

(4) Identification of emergency situations or other circumstances in which a practitioner may prescribe, dispense, and administer a prescription drug specified in section 8.1 of this chapter without a written prescription or on a form other than a form specified in section 8.1(a)(4) of this chapter.

(b) The board may:

- (1) set standards for education courses for individuals authorized to use the INSPECT program;
- (2) identify treatment programs for individuals addicted to controlled substances **or prescription drugs** monitored by the INSPECT program; and
- (3) work with impaired practitioner associations to provide intervention and treatment.

SECTION 14. [EFFECTIVE JULY 1, 2013] **(a) As used in this SECTION, "commission" refers to the health finance commission established by IC 2-5-23-3.**

**(b) During the 2013 legislative interim, the commission shall study the issue of the use of methadone and opioids in treatment programs and clinic settings.**

**(c) Not later than September 1, 2013, the division of mental health and addiction shall provide the commission with the following information in writing:**

- (1) The number of patients served in Indiana opioid treatment programs certified under IC 12-23-18.**
- (2) The opioid treatment medications provided to patients, including the dosage.**
- (3) The drug testing protocol of Indiana opioid treatment programs.**
- (4) The number of opioid treatment program patients who have tested positive for other controlled substances during a drug test for a controlled substance provided by an opioid treatment program.**
- (5) The number of opioid treatment program patients who are subsequently determined to no longer need the assistance of the opioid treatment program and released from treatment.**
- (6) Any other information requested by the commission or that is determined by the division of mental health and**

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addition to be relevant to the study described in this SECTION.

**(d) This SECTION expires December 31, 2013."**

Re-number all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 272 as introduced.)

MILLER PATRICIA, Chairperson

Committee Vote: Yeas 9, Nays 2.

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SENATE MOTION

Madam President: I move that Senate Bill 272 be amended to read as follows:

Page 1, line 12, delete "Before" and insert **"During the 2013 legislative interim, the Indiana professional licensing agency shall report to the health finance commission established by IC 2-5-23-3 concerning how to implement a program to require, before"**.

Page 1, line 13, delete "shall" and insert **"to"**.

Page 2, line 11, after "The" insert **"report must include whether to require the"**.

Page 2, line 11, delete "shall" and insert **"to"**.

Page 3, line 29, delete "2014," and insert **"2015,"**.

Page 3, line 37, delete "2014," and insert **"2015,"**.

Page 4, line 7, delete "2014," and insert **"2015,"**.

Page 4, line 12, delete "2014," and insert **"2015,"**.

Page 4, line 25, delete "2014," and insert **"2015,"**.

Page 4, line 29, delete "2014," and insert **"2015,"**.

Page 5, line 14, delete "2014," and insert **"2015,"**.

Page 10, line 2, delete "2014," and insert **"2015,"**.

Page 10, line 39, delete "by" and insert **"under"**.

(Reference is to SB 272 as printed February 8, 2013.)

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SENATE MOTION

Madam President: I move that Engrossed Senate Bill 272, which is eligible for third reading, be returned to second reading for purposes of amendment.

MILLER PATRICIA

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SENATE MOTION

Madam President: I move that Senate Bill 272 be amended to read as follows:

Page 4, line 20, delete "2014," and insert "**2015**,".

Page 10, line 29, delete "issue of the" and insert "**following**:"

**(1) The expansion of the INSPECT (as defined by IC 35-48-7-5.2) program, including:**

**(A) requiring real time reporting of collected information;**

**(B) studying the confidentiality issues concerning access to the INSPECT database;**

**(C) requiring health care practitioners who prescribe medications to report all legend drugs and the proper time frame to require the reporting; and**

**(D) having health care providers access information in the INSPECT database that would assist the health care practitioner in the treatment of patients.**

**(2) The"**

(Reference is to SB 272 as reprinted February 13, 2013.)

MILLER PATRICIA

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COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred Senate Bill 272, 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, delete lines 1 through 17.

Delete pages 2 through 9.

Page 10, delete lines 1 through 24, begin a new paragraph and insert:

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"SECTION 1. IC 16-18-2-35.8 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION** TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 35.8. "Biological product", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-1.**

SECTION 2. IC 16-18-2-36.2 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION** TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 36.2. "Biosimilar", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-2.**

SECTION 3. IC 16-18-2-191.2 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION** TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 191.2. "Interchangeable", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-3.**

SECTION 4. IC 16-18-2-288 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 288. (a) "Practitioner", for purposes of IC 16-42-19, has the meaning set forth in IC 16-42-19-5.

(b) "Practitioner", for purposes of IC 16-41-14, has the meaning set forth in IC 16-41-14-4.

(c) "Practitioner", for purposes of IC 16-42-21, has the meaning set forth in IC 16-42-21-3.

(d) "Practitioner", for purposes of IC 16-42-22 **and IC 16-42-25**, has the meaning set forth in IC 16-42-22-4.5.

SECTION 5. IC 16-18-2-313.5 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION** TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 313.5. "Reference product", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-4.**

SECTION 6. IC 16-42-22-8, AS AMENDED BY P.L.204-2005, SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 8. (a) For substitution to occur for a prescription other than a prescription filled under the Medicaid program (42 U.S.C. 1396 et seq.), the children's health insurance program established under IC 12-17.6-2, **the biosimilar biological products requirements under IC 16-42-25**, or the Medicare program (42 U.S.C. 1395 et seq.):

(1) the practitioner must:

(A) sign on the line under which the words "May substitute" appear; or

(B) for an electronically transmitted prescription, electronically transmit the instruction "May substitute."; and

(2) the pharmacist must inform the customer of the substitution.

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(b) This section does not authorize any substitution other than substitution of a generically equivalent drug product.

SECTION 7. IC 16-42-25 IS ADDED TO THE INDIANA CODE AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]:

**Chapter 25. Drugs: Biosimilar Biological Products**

**Sec. 1. As used in this chapter, "biological product" means:**

- (1) a virus;
  - (2) a therapeutic serum;
  - (3) a toxin;
  - (4) an antitoxin;
  - (5) a vaccine;
  - (6) blood;
  - (7) a blood component;
  - (8) a blood derivative;
  - (9) an allergenic product;
  - (10) a protein (except any chemically synthesized polypeptide);
  - (11) a product analogous to a product described in subdivisions (1) through (10);
  - (12) arsphenamine;
  - (13) an arsphenamine derivative; or
  - (14) any other trivalent organic arsenic compound;
- applicable to the prevention, treatment, or cure of a disease or condition for human beings.

**Sec. 2. As used in this chapter, "biosimilar" means a biological product that:**

- (1) has been licensed as a biosimilar product under 42 U.S.C. 262(k); and
- (2) is highly similar to the reference product, with:
  - (A) no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product; and
  - (B) only minor differences in clinically inactive components.

**Sec. 3. As used in this chapter, "interchangeable" means a determination by the federal Food and Drug Administration that a biosimilar product may be substituted for a reference product without the intervention of the health care provider that prescribed the biological product.**

**Sec. 4. As used in this chapter, "reference product" means the single biological product licensed under 42 U.S.C. 262(a) against**

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which a biological product is evaluated in an application submitted under 42 U.S.C. 262(k).

**Sec. 5. A pharmacist may substitute a biosimilar product for a prescribed biological product if the following conditions are met:**

- (1) The biosimilar product has been determined by the federal Food and Drug Administration to be interchangeable with the prescribed biological product.**
- (2) The prescribing practitioner has:**
  - (A) for a written prescription, signed on the line under which the words "May substitute." appear; or**
  - (B) for an electronically transmitted prescription, electronically transmitted the instruction "May substitute."**
- (3) The pharmacist has informed the customer of the substitution.**
- (4) The pharmacist notifies the prescribing practitioner, orally, in writing, or electronically, within five (5) calendar days of the substitution.**
- (5) The pharmacy and the prescribing practitioner retain a written or electronic record of the interchangeable biosimilar substitution for at least five (5) years.**

**Sec. 6. (a) The Indiana board of pharmacy shall maintain a public Internet web site that contains a current list of biosimilar biological products that the federal Food and Drug Administration has determined to be interchangeable.**

**(b) The Indiana board of pharmacy may adopt rules under IC 4-22-2 necessary to implement this chapter.**

**Sec. 7. A written or electronic prescription for a biological product must comply with the requirements under IC 16-42-22-6."**

Page 11, between lines 20 and 21, begin a new paragraph and insert:

**"(d) During the 2013 legislative interim, the commission shall study how Indiana law should address the prescribing and substituting of biosimilar biological products for other drugs."**

Page 11, line 21, delete "(d)" and insert "(e)".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 272 as reprinted February 22, 2013.)

CLERE, Chair

Committee Vote: yeas 10, nays 2.

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