Reprinted
February 4, 2011

HOUSE BILL No. 1121

DIGEST OF HB 1121 (Updated February 3, 2011 11:51 am - DI 107)

Citations Affected: IC 4-22; IC 16-28; IC 16-42; IC 25-26; IC 34-30.

Synopsis: Unused medication. Requires the board of pharmacy to adopt rules concerning a returning unused medication program (program). Provides civil liability immunity for an entity or employee of an entity who participates in a program, except for certain intentional misconduct and the enforcement of certain rules.

Effective: July 1, 2011.

Mahan, Reske, Frye R, Brown C

January 6, 2011, read first time and referred to Committee on Public Health.
January 27, 2011, reported — Do Pass.
February 3, 2011, read second time, amended, ordered engrossed.

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First Regular Session 117th General Assembly (2011)

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 2010 Regular Session of the General Assembly.

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HOUSE BILL No. 1121

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 4-22-2-37.1, AS AMENDED BY P.L.35-2010, SECTION 2, AND AS AMENDED BY P.L.113-2010, SECTION 9, IS CORRECTED AND AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2011]: Sec. 37.1. (a) This section applies to a rulemaking action resulting in any of the following rules:

(1) An order adopted by the commissioner of the Indiana department of transportation under IC 9-20-1-3(d) or IC 9-21-4-7(a) and designated by the commissioner as an emergency rule.

(2) An action taken by the director of the department of natural resources under IC 14-22-2-6(d) or IC 14-22-6-13.

(3) An emergency temporary standard adopted by the occupational safety standards commission under IC 22-8-1.1-16.1.

(4) An emergency rule adopted by the solid waste management board under IC 13-22-2-3 and classifying a waste as hazardous.

(5) A rule, other than a rule described in subdivision (6), adopted

by the department of financial institutions under IC 24-4.5-6-107 and declared necessary to meet an emergency.

(6) A rule required under IC 24-4.5-1-106 that is adopted by the department of financial institutions and declared necessary to meet an emergency under IC 24-4.5-6-107.

(7) A rule adopted by the Indiana utility regulatory commission to address an emergency under IC 8-1-2-113.

(8) An emergency rule adopted by the state lottery commission under IC 4-30-3-9.

(9) A rule adopted under IC 16-19-3-5 or IC 16-41-2-1 that the executive board of the state department of health declares is necessary to meet an emergency.

(10) An emergency rule adopted by the Indiana finance authority under IC 8-21-12.

(11) An emergency rule adopted by the insurance commissioner under IC 27-1-23-7.

(12) An emergency rule adopted by the Indiana horse racing commission under IC 4-31-3-9.

(13) An emergency rule adopted by the air pollution control board, the solid waste management board, or the water pollution control board under IC 13-15-4-10(4) or to comply with a deadline required by or other date provided by federal law, provided:

(A) the variance procedures are included in the rules; and

(B) permits or licenses granted during the period the emergency rule is in effect are reviewed after the emergency rule expires.

(14) An emergency rule adopted by the Indiana election commission under IC 3-6-4.1-14.

(15) An emergency rule adopted by the department of natural resources under IC 14-10-2-5.

(16) An emergency rule adopted by the Indiana gaming commission under IC 4-32.2-3-3(b), IC 4-33-4-2, IC 4-33-4-3, IC 4-33-4-14, *IC 4-33-22-12,* or IC 4-35-4-2.

(17) An emergency rule adopted by the alcohol and tobacco commission under IC 7.1-3-17.5, IC 7.1-3-17.7, or IC 7.1-3-20-24.4.

(18) An emergency rule adopted by the department of financial institutions under IC 28-15-11.

(19) An emergency rule adopted by the office of the secretary of family and social services under IC 12-8-1-12.

(20) An emergency rule adopted by the office of the children's

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health insurance program under IC 12-17.6-2-11.

(21) An emergency rule adopted by the office of Medicaid policy and planning under IC 12-15-41-15.

(22) An emergency rule adopted by the Indiana state board of animal health under IC 15-17-10-9.

(23) An emergency rule adopted by the board of directors of the Indiana education savings authority under IC 21-9-4-7.

(24) An emergency rule adopted by the Indiana board of tax review under IC 6-1.1-4-34 (repealed).

(25) An emergency rule adopted by the department of local government finance under IC 6-1.1-4-33 (repealed).

(26) An emergency rule adopted by the boiler and pressure vessel rules board under IC 22-13-2-8(c).

(27) An emergency rule adopted by the Indiana board of tax review under IC 6-1.1-4-37(l) (repealed) or an emergency rule adopted by the department of local government finance under IC 6-1.1-4-36(j) (repealed) or IC 6-1.1-22.5-20.

(28) An emergency rule adopted by the board of the Indiana economic development corporation under IC 5-28-5-8.

(29) A rule adopted by the department of financial institutions under IC 34-55-10-2.5.

(30) A rule adopted by the Indiana finance authority:

(A) under IC 8-15.5-7 approving user fees (as defined in IC 8-15.5-2-10) provided for in a public-private agreement under IC 8-15.5;

(B) under IC 8-15-2-17.2(a)(10):

(i) establishing enforcement procedures; and

(ii) making assessments for failure to pay required tolls;

(C) under IC 8-15-2-14(a)(3) authorizing the use of and establishing procedures for the implementation of the collection of user fees by electronic or other nonmanual means; or

(D) to make other changes to existing rules related to a toll road project to accommodate the provisions of a public-private agreement under IC 8-15.5.

(31) An emergency rule adopted by the board of the Indiana health informatics corporation under IC 5-31-5-8.

~~*(32) An emergency rule adopted by the state athletic commission under IC 25-9-1-4.5.*~~

~~*(32)*~~ ~~*(33)*~~ **(32)** An emergency rule adopted by the department of child services under IC 31-25-2-21, IC 31-27-2-4, IC 31-27-4-2, or IC 31-27-4-3.

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~~(34)~~ *(33)* An emergency rule adopted by the Indiana real estate commission under IC 25-34.1-2-5(15).

~~(35)~~ **(34)** *A rule adopted by the department of financial institutions under IC 24-4.4-1-101 and determined necessary to meet an emergency.*

(35) An emergency rule adopted by the state board of pharmacy regarding returning unused medication under IC 25-26-23.

(b) The following do not apply to rules described in subsection (a):

(1) Sections 24 through 36 of this chapter.

(2) IC 13-14-9.

(c) After a rule described in subsection (a) has been adopted by the agency, the agency shall submit the rule to the publisher for the assignment of a document control number. The agency shall submit the rule in the form required by section 20 of this chapter and with the documents required by section 21 of this chapter. The publisher shall determine the format of the rule and other documents to be submitted under this subsection.

(d) After the document control number has been assigned, the agency shall submit the rule to the publisher for filing. The agency shall submit the rule in the form required by section 20 of this chapter and with the documents required by section 21 of this chapter. The publisher shall determine the format of the rule and other documents to be submitted under this subsection.

(e) Subject to section 39 of this chapter, the publisher shall:

(1) accept the rule for filing; and

(2) electronically record the date and time that the rule is accepted.

(f) A rule described in subsection (a) takes effect on the latest of the following dates:

(1) The effective date of the statute delegating authority to the agency to adopt the rule.

(2) The date and time that the rule is accepted for filing under subsection (e).

(3) The effective date stated by the adopting agency in the rule.

(4) The date of compliance with every requirement established by law as a prerequisite to the adoption or effectiveness of the rule.

(g) Subject to subsection (h), IC 14-10-2-5, IC 14-22-2-6, IC 22-8-1.1-16.1, and IC 22-13-2-8(c), and except as provided in subsections (j), (k), and (l), a rule adopted under this section expires not later than ninety (90) days after the rule is accepted for filing under subsection (e). Except for a rule adopted under subsection (a)(13),

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(a)(24), (a)(25), or (a)(27), the rule may be extended by adopting another rule under this section, but only for one (1) extension period. The extension period for a rule adopted under subsection (a)(28) may not exceed the period for which the original rule was in effect. A rule adopted under subsection (a)(13) may be extended for two (2) extension periods. Subject to subsection (j), a rule adopted under subsection (a)(24), (a)(25), or (a)(27) may be extended for an unlimited number of extension periods. Except for a rule adopted under subsection (a)(13), for a rule adopted under this section to be effective after one (1) extension period, the rule must be adopted under:

(1) sections 24 through 36 of this chapter; or

(2) IC 13-14-9;

as applicable.

(h) A rule described in subsection (a)(8), (a)(12), or (a)(29) expires on the earlier of the following dates:

(1) The expiration date stated by the adopting agency in the rule.

(2) The date that the rule is amended or repealed by a later rule adopted under sections 24 through 36 of this chapter or this section.

(i) This section may not be used to readopt a rule under IC 4-22-2.5.

(j) A rule described in subsection (a)(24) or (a)(25) expires not later than January 1, 2006.

(k) A rule described in subsection (a)(28) expires on the expiration date stated by the board of the Indiana economic development corporation in the rule.

(l) A rule described in subsection (a)(30) expires on the expiration date stated by the Indiana finance authority in the rule.

(m) A rule described in subsection (a)(5) or (a)(6) expires on the date the department is next required to issue a rule under the statute authorizing or requiring the rule.

SECTION 2. IC 16-28-11-4, AS AMENDED BY P.L.204-2005, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2011]: Sec. 4. **(a)** A health facility that possesses unused medication that meets the requirements of IC 25-26-13-25(j)(1) through IC 25-26-13-25(j)(6):

(1) shall return medication that belonged to a Medicaid recipient; and

(2) may return other unused medication;

to the pharmacy that dispensed the medication.

(b) An entity participating in a program under IC 25-26-23 may return unused medication to the pharmacy that dispensed the medication if the board of pharmacy adopts a rule allowing this

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procedure under IC 25-26-23-2.

SECTION 3. IC 16-42-19-13 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2011]: Sec. 13. A person may not possess or use a legend drug or a precursor unless the person obtains the drug:

(1) on the prescription or drug order of a practitioner; ~~or~~

(2) in accordance with section 11(2) or 21 of this chapter; **or**

(3) in accordance with rules adopted by the board of pharmacy under IC 25-26-23.

SECTION 4. IC 25-26-23 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2011]:

Chapter 23. Returning Unused Medication

Sec. 1. For purposes of this chapter, "board" means the Indiana board of pharmacy.

Sec. 2. (a) The board shall adopt rules under IC 4-22-2 to implement this chapter.

(b) The board may adopt emergency rules under IC 4-22-2-37.1 to implement this chapter.

Sec. 3. The board shall determine the entities that may participate in a program under this chapter, but must include health facilities licensed under IC 16-28 and pharmacies.

Sec. 4. The rules adopted under this chapter must set forth the guidelines for an entity to accept unused medication. The rules must set forth:

(1) the responsibilities of the entities who are accepting the unused medication;

(2) details concerning record keeping of the medication collected;

(3) the proper methods to destroy unused medication;

(4) privacy protocols;

(5) security standards; and

(6) proper transportation procedures.

Sec. 5. The board may adopt rules:

(1) permitting unused medication to be returned through the mail; and

(2) allowing an entity determined under section 3 of this chapter to return unused medication to the pharmacy that dispensed the medication as described in IC 16-28-11-4(b).

Sec. 6. The board shall consult with the following agencies and task force in promulgating rules under this chapter:

(1) The department of environmental management.

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(2) The state department of health.
(3) The state police department.
(4) The Indiana hazardous waste task force.

Sec. 7. The rules adopted under this chapter may not:

(1) mandate an entity to establish or maintain a program under this chapter;
(2) mandate that law enforcement participate in a program under this chapter;
(3) require any new licensing or fees for a program under this chapter;
(4) create liability for a patient not using a program under this chapter; and
(5) have a fiscal impact to the state or any state agencies.

Sec. 8. (a) An entity or employee of an entity described in section 3 of this chapter who is operating a program under this chapter is immune from civil liability for an act or omission related to the operation of the program.

(b) The civil immunity described in subsection (a) does not apply to:

(1) an act or omission that constitutes gross negligence or willful, wanton, or intentional misconduct; and
(2) the enforcement of rules adopted under this chapter by a government entity.

SECTION 5. IC 34-30-2-101.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2011]: **Sec. 101.8. IC 25-26-23-8 (Concerning an entity participating in a returning unused medication program).**

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COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1121, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill do pass.

BROWN T, Chair

Committee Vote: yeas 11, nays 0.

HOUSE MOTION

Mr. Speaker: I move that House Bill 1121 be amended to read as follows:

Page 7, line 19, delete "to" and insert "**to:**
(1)".

Page 7, line 20, delete "misconduct." and insert "**misconduct; and**".
(2) the enforcement of rules adopted under this chapter by a government entity.".

(Reference is to HB 1121 as printed January 28, 2011.)

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