



Reprinted
March 1, 2012

ENGROSSED SENATE BILL No. 407

DIGEST OF SB 407 (Updated February 29, 2012 12:08 pm - DI 77)

Citations Affected: IC 25-26.

Synopsis: Pharmacies. Allows a hospital holding a Type II pharmacy permit to offer drugs and devices to certain individuals who work or volunteer at the hospital and their dependants. Allows a pharmacist to supervise not more than six licensed pharmacy technicians or pharmacy technicians in training at any time. (Currently, a pharmacist may supervise not more than four licensed pharmacy technicians or pharmacy technicians in training.) Requires a pharmacy to post notice concerning relief from discrimination against blind or visually impaired customers. Prohibits the Indiana board of pharmacy from issuing a pharmacy technician certificate to an individual who has been convicted of a felony involving controlled substances. Specifies pharmacy audit requirements, including notice procedures and limitations on an initial audit and onsite audits. Requires a period of at least 30 days during which a pharmacy may appeal preliminary audit report findings. Provides for the correction of clerical errors.

Effective: July 1, 2012.

Grooms, Breaux

(HOUSE SPONSORS — WELCH, DAVISSON, STEMLER)

January 9, 2012, read first time and referred to Committee on Health and Provider Services.

January 26, 2012, amended, reported favorably — Do Pass.

January 30, 2012, read second time, ordered engrossed. Engrossed.

February 1, 2012, read third time, passed. Yeas 49, nays 0.

HOUSE ACTION

February 13, 2012, read first time and referred to Committee on Public Health.

February 23, 2012, reported — Do Pass.

February 29, 2012, read second time, amended, ordered engrossed.

ES 407—LS 6627/DI 14+



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Second Regular Session 117th General Assembly (2012)

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 2011 Regular Session of the General Assembly.

ENGROSSED SENATE BILL No. 407

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

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

- 1 SECTION 1. IC 25-26-13-17, AS AMENDED BY P.L.98-2006,
2 SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
3 JULY 1, 2012]: Sec. 17. (a) The board shall establish classes of
4 pharmacy permits as follows:
5 Type I. A retail permit for a pharmacy that provides
6 pharmaceutical care to the general public by the dispensing of a
7 drug or device.
8 Type II. An institutional permit for hospitals, clinics, health care
9 facilities, sanitariums, nursing homes, or dispensaries that offer
10 pharmaceutical care by dispensing a drug product to an inpatient
11 under a drug order or to an outpatient of the institution under a
12 prescription.
13 Type III. A permit for a pharmacy that is not:
14 (A) open to the general public; or
15 (B) located in an institution listed under a Type II permit;
16 and provides pharmaceutical care to a patient who is located in an
17 institution or in the patient's home.

ES 407—LS 6627/DI 14+



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1 Type IV. A permit for a pharmacy not open to the general public
 2 that provides pharmaceutical care by dispensing drugs and
 3 devices to patients exclusively through the United States Postal
 4 Services or other parcel delivery service.

5 Type V. A permit for a pharmacy that engages exclusively in the
 6 preparation and dispensing of diagnostic or therapeutic
 7 radioactive drugs.

8 Type VI. A permit for a pharmacy open to the general public that
 9 provides pharmaceutical care by engaging in an activity under a
 10 Type I or Type III permit. A pharmacy that obtains a Type VI
 11 permit may provide services to:

- 12 (A) a home health care patient;
- 13 (B) a long term care facility; or
- 14 (C) a member of the general public.

15 (b) ~~Hospitals~~ **A hospital** holding a Type II permit may offer drugs
 16 or devices:

17 (1) to:

- 18 (A) an employee, student, **or volunteer of the hospital;**
- 19 (B) **a retiree who is participating in a retirement, pension,**
 20 **or benefit program administered by the hospital;**
- 21 (C) **an independent contractor who has an exclusive**
 22 **relationship with the hospital;**
- 23 (D) **a member of the hospital's governing board; or**
- 24 (E) **a member of the hospital's medical staff; member or their**
 25 **and**

26 (2) **to dependents of the individuals listed in subdivision (1);**
 27 for their own use.

28 (c) Nothing in this section prohibits a pharmacy holding a permit
 29 other than a Type IV permit from delivering drugs or devices through
 30 mail, parcel delivery, or hand delivery.

31 (d) Hospitals holding a Type II permit may operate remote locations
 32 within a reasonable distance of the licensed area, as determined by the
 33 board, after:

- 34 (1) filing an application on a form prepared by the board;
- 35 (2) having each location inspected by the board; and
- 36 (3) obtaining approval from the board.

37 (e) Any applicable rule governing the practice of pharmacy in
 38 Indiana shall apply to all permits under this section.

39 SECTION 2. IC 25-26-13-18, AS AMENDED BY P.L.1-2009,
 40 SECTION 142, IS AMENDED TO READ AS FOLLOWS
 41 [EFFECTIVE JULY 1, 2012]: Sec. 18. (a) To be eligible for issuance
 42 of a pharmacy permit, an applicant must show to the satisfaction of the

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- 1 board that:
- 2 (1) Persons at the location will engage in the bona fide practice of
- 3 pharmacy. The application must show the number of hours each
- 4 week, if any, that the pharmacy will be open to the general public.
- 5 (2) The pharmacy will maintain a sufficient stock of emergency
- 6 and frequently prescribed drugs and devices as to adequately
- 7 serve and protect the public health.
- 8 (3) Except as provided in section 19 of this chapter, a registered
- 9 pharmacist will be in personal attendance and on duty in the
- 10 licensed premises at all times when the practice of pharmacy is
- 11 being conducted and that the pharmacist will be responsible for
- 12 the lawful conduct of the pharmacy.
- 13 (4) ~~One (1) pharmacist will have not more than four~~ (4) Certified
- 14 pharmacy technicians or pharmacy technicians in training
- 15 certified under IC 25-26-19 **must practice under the a licensed**
- 16 **pharmacist's immediate and personal supervision at any time. all**
- 17 **times. A pharmacist may not supervise more than six (6)**
- 18 **pharmacy technicians or pharmacy technicians in training at**
- 19 **any time.** As used in this ~~clause, subdivision,~~ "immediate and
- 20 personal supervision" means within reasonable visual and vocal
- 21 distance of the pharmacist.
- 22 (5) The pharmacy will be located separate and apart from any area
- 23 containing merchandise not offered for sale under the pharmacy
- 24 permit. The pharmacy will:
- 25 (A) be stationary;
- 26 (B) be sufficiently secure, either through electronic or physical
- 27 means, or a combination of both, to protect the products
- 28 contained in the pharmacy and to detect and deter entry during
- 29 those times when the pharmacy is closed;
- 30 (C) be well lighted and ventilated with clean and sanitary
- 31 surroundings;
- 32 (D) be equipped with a sink with hot and cold running water
- 33 or some means for heating water, a proper sewage outlet, and
- 34 refrigeration;
- 35 (E) have a prescription filling area of sufficient size to permit
- 36 the practice of pharmacy as practiced at that particular
- 37 pharmacy; and
- 38 (F) have such additional fixtures, facilities, and equipment as
- 39 the board requires to enable it to operate properly as a
- 40 pharmacy in compliance with federal and state laws and
- 41 regulations governing pharmacies.
- 42 (b) Prior to opening a pharmacy after receipt of a pharmacy permit,

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1 the permit holder shall submit the premises to a qualifying inspection
2 by a representative of the board and shall present a physical inventory
3 of the drug and all other items in the inventory on the premises.

4 (c) At all times, the wholesale value of the drug inventory on the
5 licensed items must be at least ten percent (10%) of the wholesale
6 value of the items in the licensed area.

7 SECTION 3. IC 25-26-13-18.5 IS ADDED TO THE INDIANA
8 CODE AS A NEW SECTION TO READ AS FOLLOWS
9 [EFFECTIVE JULY 1, 2012]: Sec. 18.5. (a) This section applies to a
10 pharmacy customer who is blind (as defined in IC 12-7-2-21(2)) or
11 visually impaired (as defined in IC 12-7-2-198(a)).

12 (b) A pharmacy shall post in a conspicuous place in the area
13 where customers receive legend drugs dispensed by the pharmacy
14 a single page poster providing customers with notice of the
15 following information:

16 (1) That federal law requires that a pharmacy ensure that a
17 customer who is blind or visually impaired is not subject to
18 discrimination in the availability of visually delivered
19 information provided by the pharmacy.

20 (2) That a customer who is blind or visually impaired and who
21 has reasonable grounds to believe that the customer has been
22 or may be subject to discrimination described in subdivision

23 (1) may:

24 (A) submit a request to the federal Department of Justice
25 to institute an investigation into the matter; or

26 (B) institute a private civil action for relief.

27 The poster must include current contact information for the
28 federal Department of Justice where a customer may obtain
29 further information and submit a request for an investigation as
30 described in subdivision (2).

31 (c) A pharmacist or pharmacy technician shall read the
32 information contained in the notice required by subsection (b) to
33 a customer described in subsection (a) each time the customer
34 receives a legend drug dispensed by the pharmacy.

35 (d) A pharmacy shall provide a written copy of the notice
36 required by subsection (b) to any individual upon request.

37 SECTION 4. IC 25-26-19-5 IS AMENDED TO READ AS
38 FOLLOWS [EFFECTIVE JULY 1, 2012]: Sec. 5. (a) The board shall
39 issue a pharmacy technician certificate to an individual who:

40 (1) applies to the board in the form and manner prescribed by the
41 board;

42 (2) is at least eighteen (18) years of age;

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- 1 (3) has not been convicted of:
- 2 (A) a crime that has a direct bearing upon the individual's
- 3 ability to practice competently; or
- 4 (B) a felony involving controlled substances;
- 5 (4) is not in violation of this chapter or rules adopted by the board
- 6 under section 4 of this chapter;
- 7 (5) has paid the fee set by the board under section 4 of this
- 8 chapter; and
- 9 (6) has completed a program of education and training approved
- 10 by the board or has passed a certification examination offered by
- 11 a nationally recognized certification body approved by the board.

12 (b) For good cause, the board may waive the age requirement under
 13 subsection (a)(2).

14 SECTION 5. IC 25-26-22-4.2 IS ADDED TO THE INDIANA
 15 CODE AS A NEW SECTION TO READ AS FOLLOWS
 16 [EFFECTIVE JULY 1, 2012]: **Sec. 4.2. (a) A third party payer may**
 17 **cause an onsite audit to occur at a particular pharmacy location**
 18 **not more than one (1) time per calendar year.**

19 (b) **A company that conducts an audit for a third party payer**
 20 **may conduct an onsite audit at a particular pharmacy location not**
 21 **more than one (1) time per calendar year for each third party**
 22 **payer. However, if the audit results in a finding of a particular**
 23 **problem at the pharmacy, the auditor may return within the**
 24 **calendar year to determine ongoing compliance.**

25 SECTION 6. IC 25-26-22-5, AS ADDED BY P.L.7-2009,
 26 SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 27 JULY 1, 2012]: **Sec. 5. An auditor conducting an audit shall comply**
 28 **with all of the following:**

- 29 (1) The contract under which the audit is performed must provide
- 30 a description of audit procedures that will be followed.
- 31 (2) For an onsite audit conducted at a pharmacy's location, the
- 32 auditor that conducts the audit shall provide written notice to the
- 33 pharmacy at least two (2) weeks before the initial onsite audit is
- 34 performed for each audit cycle.
- 35 (3) The auditor shall not interfere with the delivery of pharmacist
- 36 services to a patient and shall use every effort to minimize
- 37 inconvenience and disruption to pharmacy operations during the
- 38 audit. This subdivision does not prohibit audits during normal
- 39 business hours of the pharmacy.
- 40 (4) If the audit requires use of clinical or professional judgment,
- 41 the audit must be conducted by or in consultation with a licensed
- 42 pharmacist.

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1 (5) The auditor shall allow the use of written or otherwise
2 transmitted hospital, physician, or other health practitioner
3 records to validate a pharmacy record with respect to a
4 prescription for a legend drug.

5 (6) The auditor shall perform the audit according to the same
6 standards and parameters that the auditor uses to audit all other
7 similarly situated pharmacies on behalf of the third party payer.

8 (7) The period covered by the audit must not exceed twenty-four
9 (24) months after the date on which the claim that is the subject
10 of the audit was submitted to or adjudicated by the third party
11 payer, and the pharmacy must be permitted to resubmit
12 electronically any claims disputed by the audit. This subdivision
13 does not limit the period for audits under the Medicaid program
14 that are conducted due to a federal requirement.

15 (8) The audit must not be initiated or scheduled during the first
16 ~~five (5)~~ **seven (7)** calendar days of any month without the
17 voluntary consent of the pharmacy. The consent may not be
18 mandated by a contract or any other means.

19 (9) Payment to the onsite auditor for conducting the audit must
20 not be based on a percentage of any amount recovered as a result
21 of the audit.

22 **(10) Within twenty-four (24) hours of receiving the notice of**
23 **an audit, a pharmacy may reschedule the audit to a date not**
24 **more than fourteen (14) days after the date proposed by the**
25 **auditor. However, if the auditor is unable to reschedule within**
26 **the fourteen (14) day period, the auditor shall select and**
27 **reschedule the audit for a date after the fourteen (14) day**
28 **period.**

29 **(11) This subdivision does not apply to an audit conducted by**
30 **the Medicaid program. If a clerical error is identified by the**
31 **auditor during the course of an audit, the auditor shall allow**
32 **the pharmacy to obtain a prescription that corrects the**
33 **clerical error from the prescribing physician. However, if the**
34 **clerical error results in an overpayment to the pharmacy, the**
35 **overpayment may be recouped by the third party payer.**

36 SECTION 7. IC 25-26-22-6, AS ADDED BY P.L.7-2009,
37 SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
38 JULY 1, 2012]: Sec. 6. **(a) This section does not apply to an audit**
39 **conducted by the Medicaid, Medicare, or any other federal**
40 **program.**

41 **(b)** Following an audit, the auditor shall provide to the pharmacy
42 written audit reports as follows:

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- 1 (1) The auditor shall deliver a preliminary audit report to the
 2 pharmacy not later than ninety (90) days after the audit is
 3 concluded.
- 4 (2) The auditor shall provide with the preliminary audit report a
 5 written appeal procedure for the pharmacy to follow if the
 6 pharmacy desires to appeal a finding contained in the preliminary
 7 audit report. **The written appeal procedure must provide for a**
 8 **period of at least thirty (30) days after the pharmacy receives**
 9 **the preliminary audit report during which the pharmacy may**
 10 **file an appeal of findings contained in the preliminary audit**
 11 **report.**
- 12 (3) The auditor shall deliver a final audit report to the pharmacy
 13 not later than one hundred twenty (120) days after:
- 14 (A) the preliminary audit report is received by the pharmacy;
 15 or
- 16 (B) if an appeal is filed, a final appeal determination is made;
 17 whichever is later.
- 18 (4) Each audit report must be signed by the auditor and a
 19 pharmacist participating in the audit.
- 20 (5) The auditor shall provide a copy of the final audit report to the
 21 third party payer.
- 22 **(c) An audit report provided to a pharmacy under this section**
 23 **must be sent to the pharmacy by a means that allows signature**
 24 **confirmation, including an electronic signature (as defined by**
 25 **IC 25-26-13-2). If the audit report is sent by electronic mail, any**
 26 **other verification system may be used, provided that the receipt is**
 27 **acknowledged by the pharmacy.**
- 28 SECTION 8. IC 25-26-22-9, AS ADDED BY P.L.7-2009,
 29 SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 30 JULY 1, 2012]: Sec. 9. **(a) This section does not apply to an audit**
 31 **conducted by the Medicaid, Medicare, or any other federal**
 32 **program.**
- 33 **(a) A final audit report must first be distributed (b) Before**
 34 **recoupment of funds may be made based on an audit finding of**
 35 **overpayment or underpayment:**
- 36 **(1) a final audit report must be distributed; and**
 37 **(2) except when an audit finds that fraud, willful**
 38 **misrepresentation, or alleged serious abuse has occurred, at**
 39 **least thirty (30) days must elapse after the date on which the**
 40 **final audit report is distributed before the recoupment of**
 41 **funds exceeding ten thousand dollars (\$10,000).**
- 42 **(b) Except for audits conducted under the Medicaid program; (c)**

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- 1 Interest on funds described in subsection ~~(a)~~ (b) does not accrue during
- 2 the audit period.

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COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 407, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 2, line 4, after "times." insert "**A pharmacist may not supervise more than six (6) pharmacy technicians or pharmacy technicians in training at any time.**".

Page 2, line 4, strike "clause," and insert "**subdivision,**".

Page 2, delete lines 34 through 42, begin a new paragraph and insert:

"SECTION 2. IC 25-26-19-5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2012]: Sec. 5. (a) The board shall issue a pharmacy technician certificate to an individual who:

- (1) applies to the board in the form and manner prescribed by the board;
- (2) is at least eighteen (18) years of age;
- (3) has not been convicted of:
 - (A) a crime that has a direct bearing upon the individual's ability to practice competently; **or**
 - (B) a felony involving controlled substances;
- (4) is not in violation of this chapter or rules adopted by the board under section 4 of this chapter;
- (5) has paid the fee set by the board under section 4 of this chapter; and
- (6) has completed a program of education and training approved by the board or has passed a certification examination offered by a nationally recognized certification body approved by the board.

(b) For good cause, the board may waive the age requirement under subsection (a)(2)."

Delete page 3.

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 407 as introduced.)

MILLER, Chairperson

Committee Vote: Yeas 9, Nays 0.

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COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred Senate Bill 407, 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 9, nays 1.

 HOUSE MOTION

Mr. Speaker: I move that Engrossed Senate Bill 407 be amended to read as follows:

Page 2, between lines 35 and 36, begin a new paragraph and insert:
 "SECTION 2. IC 25-26-13-18.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2012]: **Sec. 18.5. (a) This section applies to a pharmacy customer who is blind (as defined in IC 12-7-2-21(2)) or visually impaired (as defined in IC 12-7-2-198(a)).**

(b) A pharmacy shall post in a conspicuous place in the area where customers receive legend drugs dispensed by the pharmacy a single page poster providing customers with notice of the following information:

(1) That federal law requires that a pharmacy ensure that a customer who is blind or visually impaired is not subject to discrimination in the availability of visually delivered information provided by the pharmacy.

(2) That a customer who is blind or visually impaired and who has reasonable grounds to believe that the customer has been or may be subject to discrimination described in subdivision

(1) may:

(A) submit a request to the federal Department of Justice to institute an investigation into the matter; or

(B) institute a private civil action for relief.

The poster must include current contact information for the federal Department of Justice where a customer may obtain further information and submit a request for an investigation as described in subdivision (2).

(c) A pharmacist or pharmacy technician shall read the information contained in the notice required by subsection (b) to



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a customer described in subsection (a) each time the customer receives a legend drug dispensed by the pharmacy.

(d) A pharmacy shall provide a written copy of the notice required by subsection (b) to any individual upon request."

Renumber all SECTIONS consecutively.

(Reference is to ESB 407 as printed February 24, 2012.)

FRY C

HOUSE MOTION

Mr. Speaker: I move that Engrossed Senate Bill 407 be amended to read as follows:

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

"SECTION 1. IC 25-26-13-17, AS AMENDED BY P.L.98-2006, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2012]: Sec. 17. (a) The board shall establish classes of pharmacy permits as follows:

Type I. A retail permit for a pharmacy that provides pharmaceutical care to the general public by the dispensing of a drug or device.

Type II. An institutional permit for hospitals, clinics, health care facilities, sanitariums, nursing homes, or dispensaries that offer pharmaceutical care by dispensing a drug product to an inpatient under a drug order or to an outpatient of the institution under a prescription.

Type III. A permit for a pharmacy that is not:

(A) open to the general public; or

(B) located in an institution listed under a Type II permit; and provides pharmaceutical care to a patient who is located in an institution or in the patient's home.

Type IV. A permit for a pharmacy not open to the general public that provides pharmaceutical care by dispensing drugs and devices to patients exclusively through the United States Postal Services or other parcel delivery service.

Type V. A permit for a pharmacy that engages exclusively in the preparation and dispensing of diagnostic or therapeutic radioactive drugs.

Type VI. A permit for a pharmacy open to the general public that

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provides pharmaceutical care by engaging in an activity under a Type I or Type III permit. A pharmacy that obtains a Type VI permit may provide services to:

- (A) a home health care patient;
- (B) a long term care facility; or
- (C) a member of the general public.

(b) ~~Hospitals~~ **A hospital** holding a Type II permit may offer drugs or devices:

(1) to:

- (A) an employee, student, or volunteer of the hospital;**
- (B) a retiree who is participating in a retirement, pension, or benefit program administered by the hospital;**
- (C) an independent contractor who has an exclusive relationship with the hospital;**
- (D) a member of the hospital's governing board; or**
- (E) a member of the hospital's medical staff; ~~member or their~~**
and

(2) to dependents of the individuals listed in subdivision (1);
for their own use.

(c) Nothing in this section prohibits a pharmacy holding a permit other than a Type IV permit from delivering drugs or devices through mail, parcel delivery, or hand delivery.

(d) Hospitals holding a Type II permit may operate remote locations within a reasonable distance of the licensed area, as determined by the board, after:

- (1) filing an application on a form prepared by the board;
- (2) having each location inspected by the board; and
- (3) obtaining approval from the board.

(e) Any applicable rule governing the practice of pharmacy in Indiana shall apply to all permits under this section."

Renumber all SECTIONS consecutively.

(Reference is to ESB 407 as printed February 24, 2012.)

WELCH

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HOUSE MOTION

Mr. Speaker: I move that Engrossed Senate Bill 407 be amended to read as follows:

Page 3, after line 12, begin a new paragraph and insert:

"SECTION 3. IC 25-26-22-4.2 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2012]: **Sec. 4.2. (a) A third party payer may cause an onsite audit to occur at a particular pharmacy location not more than one (1) time per calendar year.**

(b) A company that conducts an audit for a third party payer may conduct an onsite audit at a particular pharmacy location not more than one (1) time per calendar year for each third party payer. However, if the audit results in a finding of a particular problem at the pharmacy, the auditor may return within the calendar year to determine ongoing compliance.

SECTION 4. IC 25-26-22-5, AS ADDED BY P.L.7-2009, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2012]: Sec. 5. An auditor conducting an audit shall comply with all of the following:

- (1) The contract under which the audit is performed must provide a description of audit procedures that will be followed.
- (2) For an onsite audit conducted at a pharmacy's location, the auditor that conducts the audit shall provide written notice to the pharmacy at least two (2) weeks before the initial onsite audit is performed for each audit cycle.
- (3) The auditor shall not interfere with the delivery of pharmacist services to a patient and shall use every effort to minimize inconvenience and disruption to pharmacy operations during the audit. This subdivision does not prohibit audits during normal business hours of the pharmacy.
- (4) If the audit requires use of clinical or professional judgment, the audit must be conducted by or in consultation with a licensed pharmacist.
- (5) The auditor shall allow the use of written or otherwise transmitted hospital, physician, or other health practitioner records to validate a pharmacy record with respect to a prescription for a legend drug.
- (6) The auditor shall perform the audit according to the same standards and parameters that the auditor uses to audit all other similarly situated pharmacies on behalf of the third party payer.
- (7) The period covered by the audit must not exceed twenty-four (24) months after the date on which the claim that is the subject

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of the audit was submitted to or adjudicated by the third party payer, and the pharmacy must be permitted to resubmit electronically any claims disputed by the audit. This subdivision does not limit the period for audits under the Medicaid program that are conducted due to a federal requirement.

(8) The audit must not be initiated or scheduled during the first ~~five (5)~~ **seven (7)** calendar days of any month without the voluntary consent of the pharmacy. The consent may not be mandated by a contract or any other means.

(9) Payment to the onsite auditor for conducting the audit must not be based on a percentage of any amount recovered as a result of the audit.

(10) Within twenty-four (24) hours of receiving the notice of an audit, a pharmacy may reschedule the audit to a date not more than fourteen (14) days after the date proposed by the auditor. However, if the auditor is unable to reschedule within the fourteen (14) day period, the auditor shall select and reschedule the audit for a date after the fourteen (14) day period.

(11) This subdivision does not apply to an audit conducted by the Medicaid program. If a clerical error is identified by the auditor during the course of an audit, the auditor shall allow the pharmacy to obtain a prescription that corrects the clerical error from the prescribing physician. However, if the clerical error results in an overpayment to the pharmacy, the overpayment may be recouped by the third party payer.

SECTION 5. IC 25-26-22-6, AS ADDED BY P.L.7-2009, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2012]: Sec. 6. **(a) This section does not apply to an audit conducted by the Medicaid, Medicare, or any other federal program.**

(b) Following an audit, the auditor shall provide to the pharmacy written audit reports as follows:

(1) The auditor shall deliver a preliminary audit report to the pharmacy not later than ninety (90) days after the audit is concluded.

(2) The auditor shall provide with the preliminary audit report a written appeal procedure for the pharmacy to follow if the pharmacy desires to appeal a finding contained in the preliminary audit report. **The written appeal procedure must provide for a period of at least thirty (30) days after the pharmacy receives the preliminary audit report during which the pharmacy may**

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file an appeal of findings contained in the preliminary audit report.

(3) The auditor shall deliver a final audit report to the pharmacy not later than one hundred twenty (120) days after:

(A) the preliminary audit report is received by the pharmacy;
or

(B) if an appeal is filed, a final appeal determination is made; whichever is later.

(4) Each audit report must be signed by the auditor and a pharmacist participating in the audit.

(5) The auditor shall provide a copy of the final audit report to the third party payer.

(c) An audit report provided to a pharmacy under this section must be sent to the pharmacy by a means that allows signature confirmation, including an electronic signature (as defined by IC 25-26-13-2). If the audit report is sent by electronic mail, any other verification system may be used, provided that the receipt is acknowledged by the pharmacy.

SECTION 6. IC 25-26-22-9, AS ADDED BY P.L.7-2009, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2012]: Sec. 9. **(a) This section does not apply to an audit conducted by the Medicaid, Medicare, or any other federal program.**

(a) A final audit report must first be distributed (b) Before recoupment of funds may be made based on an audit finding of overpayment or underpayment:

(1) a final audit report must be distributed; and

(2) except when an audit finds that fraud, willful misrepresentation, or alleged serious abuse has occurred, at least thirty (30) days must elapse after the date on which the final audit report is distributed before the recoupment of funds exceeding ten thousand dollars (\$10,000).

(b) Except for audits conducted under the Medicaid program; (c) Interest on funds described in subsection (a) (b) does not accrue during the audit period."

Renumber all SECTIONS consecutively.

(Reference is to ESB 407 as printed February 24, 2012.)

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