



March 18, 2005

**ENGROSSED
SENATE BILL No. 590**

DIGEST OF SB 590 (Updated March 15, 2005 5:21 pm - DI 77)

Citations Affected: IC 10-13; IC 16-18; IC 16-28; IC 16-42; IC 25-26; IC 27-13; IC 34-24; IC 35-43; IC 35-48; noncode.

Synopsis: Prescription drugs. Allows the: (1) electronic transmission of prescriptions and instructions related to the prescriptions; and (2) transmission of prescriptions by facsimiles for schedule III, IV, and V controlled substances. Requires that a prescription may be transmitted electronically only through the use of an electronic data intermediary. Requires the board of pharmacy to: (1) adopt rules concerning security of electronically transmitted prescription information; and (2) establish an process for approving electronic data intermediaries. Expands the requirements that must be met by a wholesale drug distributor for eligibility for licensure. Specifies prohibited acts. Specifies criminal acts related to wholesale drug distribution and legend drugs. Allows the board of pharmacy to establish an electronic pedigree pilot program.

Effective: July 1, 2005.

Riegsecker, Simpson

(HOUSE SPONSORS — BUDAK, BROWN C)

January 20, 2005, read first time and referred to Committee on Economic Development and Technology.

January 31, 2005, reported favorably — Do Pass.

February 10, 2005, read second time, amended, ordered engrossed.

February 11, 2005, engrossed.

February 28, 2005, read third time, passed. Yeas 48, nays 0.

HOUSE ACTION

March 8, 2005, read first time and referred to Committee on Public Health.

March 17, 2005, amended, reported — Do Pass.

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March 18, 2005

First Regular Session 114th General Assembly (2005)

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 2004 Regular Session of the General Assembly.

ENGROSSED SENATE BILL No. 590

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

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

- 1 SECTION 1. IC 10-13-3-38.5 IS AMENDED TO READ AS
2 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 38.5. (a) Under federal
3 P.L.92-544 (86 Stat. 1115), the department may use an individual's
4 fingerprints submitted by the individual for the following purposes:
5 (1) Determining the individual's suitability for employment with
6 the state, or as an employee of a contractor of the state, in a
7 position:
8 (A) that has a job description that includes contact with, care
9 of, or supervision over a person less than eighteen (18) years
10 of age;
11 (B) that has a job description that includes contact with, care
12 of, or supervision over an endangered adult (as defined in
13 IC 12-10-3-2), except the individual is not required to meet the
14 standard for harmed or threatened with harm set forth in
15 IC 12-10-3-2(a)(3);
16 (C) at a state institution managed by the office of the secretary
17 of family and social services or state department of health;

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- 1 (D) at the Indiana School for the Deaf established by
- 2 IC 20-16-2-1;
- 3 (E) at the Indiana School for the Blind established by
- 4 IC 20-15-2-1;
- 5 (F) at a juvenile detention facility;
- 6 (G) with the gaming commission under IC 4-33-3-16;
- 7 (H) with the department of financial institutions under
- 8 IC 28-11-2-3; or
- 9 (I) that has a job description that includes access to or
- 10 supervision over state financial or personnel data, including
- 11 state warrants, banking codes, or payroll information
- 12 pertaining to state employees.

13 (2) Identification in a request related to an application for a
 14 teacher's license submitted to the professional standards board
 15 established under IC 20-1-1.4.

16 **(3) Use by the Indiana board of pharmacy in determining the**
 17 **individual's suitability for a position or employment with a**
 18 **wholesale drug distributor, as specified in IC 25-26-14-16(b),**
 19 **IC 25-26-14-16.5(b), IC 25-26-14-17.8(c), and IC 25-26-14-20.**

20 An applicant shall submit the fingerprints in an appropriate format or
 21 on forms provided for the employment or license application. The
 22 department shall charge each applicant the fee established under
 23 section 28 of this chapter and by federal authorities to defray the costs
 24 associated with a search for and classification of the applicant's
 25 fingerprints. The department may forward fingerprints submitted by an
 26 applicant to the Federal Bureau of Investigation or any other agency for
 27 processing. The state personnel department or the agency to which the
 28 applicant is applying for employment or a license may receive the
 29 results of all fingerprint investigations.

30 (b) An applicant who is an employee of the state may not be charged
 31 under subsection (a).

32 (c) Subsection (a)(1) does not apply to an employee of a contractor
 33 of the state if the contract involves the construction or repair of a
 34 capital project or other public works project of the state.

35 SECTION 2. IC 16-18-2-106.3 IS ADDED TO THE INDIANA
 36 CODE AS A NEW SECTION TO READ AS FOLLOWS
 37 [EFFECTIVE JULY 1, 2005]: **Sec. 106.3. For purposes of IC 16-42-3**
 38 **and IC 16-42-22, "electronic signature" means an electronic sound,**
 39 **symbol, or process:**

- 40 (1) attached to or logically associated with an electronically
- 41 transmitted prescription or order; and
- 42 (2) executed or adopted by a person;

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1 **with the intent to sign the electronically transmitted prescription**
2 **or order.**

3 SECTION 3. IC 16-18-2-106.4 IS ADDED TO THE INDIANA
4 CODE AS A NEW SECTION TO READ AS FOLLOWS
5 [EFFECTIVE JULY 1, 2005]: **Sec. 106.4. For purposes of**
6 **IC 16-42-3, IC 16-42-19, and IC 16-42-22, "electronically**
7 **transmitted" or "electronic transmission" means the transmission**
8 **of a prescription in electronic form. The term does not include**
9 **transmission of a prescription by facsimile.**

10 SECTION 4. IC 16-28-11-4 IS AMENDED TO READ AS
11 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 4. A health facility that
12 possesses unused medication that meets the requirements of
13 ~~IC 25-26-13-25(i)(1)~~ **IC 25-26-13-25(j)(1)** through
14 ~~IC 25-26-13-25(i)(6)~~ **IC 25-26-13-25(j)(6):**

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

17 (2) may return other unused medication;
18 to the pharmacy that dispensed the medication.

19 SECTION 5. IC 16-42-3-6 IS AMENDED TO READ AS
20 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 6. (a) This section
21 applies to a drug intended for use by humans that:

22 (1) is a habit forming drug to which section 4(4) of this chapter
23 applies;

24 (2) because of:

25 (A) the drug's toxicity or other potential for harmful effect;

26 (B) the method of the drug's use; or

27 (C) the collateral measures necessary to the drug's use;

28 is not safe for use except under the supervision of a practitioner
29 licensed by law to administer the drug; or

30 (3) is limited by an approved application under Section 505 of the
31 Federal Act or section 7 or 8 of this chapter to use under the
32 professional supervision of a practitioner licensed by law to
33 administer the drug.

34 (b) A drug described in subsection (a) may be dispensed only:

35 (1) upon a written **or an electronically transmitted** prescription
36 of a practitioner licensed by law to administer the drug;

37 (2) upon an oral prescription of the practitioner that is reduced
38 promptly to writing and filed by the ~~pharmacist;~~ **pharmacist or**
39 **pharmacist intern (as defined in IC 25-26-13-2);** or

40 (3) by refilling a ~~written or oral~~ prescription if the refilling is
41 authorized by the prescriber either in the original prescription, **by**
42 **an electronically transmitted order that is recorded in an**

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1 **electronic format**, or by oral order that is reduced promptly to
2 writing **or is entered into an electronic format** and filed by the
3 pharmacist **or pharmacist intern (as defined by IC 25-26-13-2)**.
4 (c) If a prescription for a drug described in subsection (a) does not
5 indicate how many times the prescription may be refilled, if any, the
6 prescription may not be refilled unless the pharmacist is subsequently
7 authorized to do so by the practitioner.
8 (d) The act of dispensing a drug contrary to subsection (a), (b), or
9 (c) is considered to be an act that results in a drug being misbranded
10 while held for sale.
11 (e) A drug dispensed by filling or refilling a ~~written or oral~~
12 prescription of a practitioner licensed by law to administer the drug is
13 exempt from the requirements of section 4(2), 4(3), 4(4), 4(5), 4(6),
14 4(7), 4(8), and 4(9) of this chapter if the drug bears a label containing
15 the following:
16 (1) The name and address of the dispenser.
17 (2) The serial number and date of the prescription or of the
18 prescription's filling.
19 (3) The name of the drug's prescriber and, if stated in the
20 prescription, the name of the patient.
21 (4) The directions for use and cautionary statements, if any,
22 contained in the prescription.
23 This exemption does not apply to any drugs dispensed in the course of
24 the conduct of a business of dispensing drugs pursuant to diagnosis by
25 mail or to a drug dispensed in violation of subsection (a), (b), (c), or
26 (d).
27 (f) The state department may adopt rules to remove drugs subject to
28 section 4(4) of this chapter, section 7 of this chapter, or section 8 of this
29 chapter from the requirements of subsections (a) through (d) when the
30 requirements are not necessary for the protection of public health.
31 Drugs removed from the prescription requirements of the Federal Act
32 by regulations issued under the Federal Act may also, by rules adopted
33 by the state department, be removed from the requirement of
34 subsections (a) through (d).
35 (g) A drug that is subject to subsections (a) through (d) is
36 considered to be misbranded if at any time before dispensing the drug's
37 label fails to bear the statement "Caution: Federal Law Prohibits
38 Dispensing Without Prescription" or "Caution: State Law Prohibits
39 Dispensing Without Prescription". A drug to which subsections (a)
40 through (d) ~~does do~~ not apply is considered to be misbranded if, at any
41 time before dispensing, the drug's label bears the caution statement
42 described in this subsection.

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1 (h) This section does not relieve a person from a requirement
2 prescribed by or under authority of law with respect to drugs included
3 within the classifications of narcotic drugs or marijuana as defined in
4 the applicable federal and state laws relating to narcotic drugs and
5 marijuana.

6 (i) **A drug may be dispensed under subsection (b) upon an**
7 **electronically transmitted prescription only to the extent permitted**
8 **by federal law.**

9 SECTION 6. IC 16-42-3-9 IS AMENDED TO READ AS
10 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 9. (a) Sections 7 and 8
11 of this chapter do not apply to the following:

12 (1) To a drug dispensed on a written **or an electronically**
13 **transmitted** prescription signed by **or with an electronic**
14 **signature of** a physician, dentist, or veterinarian (except a drug
15 dispensed in the course of the conduct of a business of dispensing
16 drugs pursuant to diagnosis by mail) if the physician, dentist, or
17 veterinarian is licensed by law to administer the drug, and the
18 drug bears a label containing the name and place of business of
19 the dispenser, the serial number and date of the prescription, and
20 the name of the physician, dentist, or veterinarian.

21 (2) To a drug exempted by rule of the state department and that is
22 intended solely for investigational use by experts qualified by
23 scientific training and experience to investigate the safety and
24 effectiveness of drugs.

25 (3) To a drug sold in Indiana or introduced into intrastate
26 commerce at any time before the enactment of the Federal Act, if
27 the drug's labeling contained the same representations concerning
28 the conditions of the drug's use.

29 (4) To any drug that is licensed under the Public Health Service
30 Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et
31 seq.) or under the Animal Virus-Serum Toxin Act of March 4,
32 1913 (13 Stat. 832; 21 U.S.C. 151 et seq.).

33 (5) To a drug subject to section 4(10) of this chapter.

34 (b) Rules exempting drugs intended for investigational use under
35 subsection (a)(2) may, within the discretion of the state department
36 among other conditions relating to the protection of the public health,
37 provide for conditioning the exemption upon the following:

38 (1) The submission to the state department, before any clinical
39 testing of a new drug is undertaken, of reports by the
40 manufacturer or the sponsor of the investigation of the drug or
41 preclinical tests, including tests on animals, of the drug adequate
42 to justify the proposed clinical testing.

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1 (2) The manufacturer or the sponsor of the investigation of a new
2 drug proposed to be distributed to investigators for clinical testing
3 obtaining a signed agreement from each of the investigators that
4 patients to whom the drug is administered will be under the
5 manufacturer's or sponsor's personal supervision or under the
6 supervision of investigators responsible to the manufacturer or
7 sponsor and that the manufacturer or sponsor will not supply the
8 drug to any other investigator or to clinics for administration to
9 human beings.

10 (3) The establishment and maintenance of the records and the
11 making of the reports to the state department by the manufacturer
12 or the sponsor of the investigation of the drug of data (including
13 analytical reports by investigators) obtained as the result of the
14 investigational use of the drug that the state department finds will
15 enable the state department to evaluate the safety and
16 effectiveness of the drug if an application is filed under section 8
17 of this chapter.

18 (c) Rules exempting drugs intended for investigational use under
19 subsection (a)(2) must provide that the exemption is conditioned upon
20 the manufacturer or the sponsor of the investigation requiring that
21 experts using the drugs for investigational purposes certify to the
22 manufacturer or sponsor that the experts will inform any human beings
23 to whom the drugs or any controls used in connection with the drugs
24 are being administered that the drugs are being used for investigational
25 purposes and will obtain the consent of the human beings or their
26 representatives, except where they consider it not feasible or, in their
27 professional judgment, contrary to the best interests of the human
28 beings.

29 (d) This section does not require a clinical investigator to submit
30 directly to the state department reports on the investigational use of
31 drugs. The regulations adopted under Section 505(i) of the Federal Act
32 are the rules in Indiana. The state may adopt rules, whether or not in
33 accordance with regulations promulgated under the Federal Act.

34 SECTION 7. IC 16-42-19-7 IS AMENDED TO READ AS
35 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 7. As used in this
36 chapter, "prescription" means:

37 (1) a written order to or for an ultimate user for a drug or device
38 containing the name and address of the patient, the name and
39 strength or size of the drug or device, the amount to be dispensed,
40 adequate directions for the proper use of the drug or device by the
41 patient, and the name of the practitioner, issued and signed by a
42 practitioner; or

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1 (2) an order transmitted by other means of communication from
2 a practitioner that is:

3 (A) immediately reduced to writing by the ~~pharmacist;~~
4 **pharmacist or pharmacist intern (as defined in**
5 **IC 25-26-13-2); or**

6 **(B) for an electronically transmitted prescription:**

7 **(i) has the electronic signature of the practitioner; and**
8 **(ii) is recorded by the pharmacist in an electronic**
9 **format.**

10 SECTION 8. IC 16-42-19-12 IS AMENDED TO READ AS
11 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 12. Except as
12 authorized under ~~IC 25-26-13-25(e)~~, **IC 25-26-13-25(d)**, a person may
13 not refill a prescription or drug order for a legend drug except in the
14 manner designated on the prescription or drug order or by the
15 authorization of the practitioner.

16 SECTION 9. IC 16-42-22-3 IS AMENDED TO READ AS
17 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 3. As used in this
18 chapter, "customer" means the individual for whom a prescription is
19 written **or electronically transmitted** or the individual's
20 representative.

21 SECTION 10. IC 16-42-22-6 IS AMENDED TO READ AS
22 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 6. **(a)** Each written
23 prescription issued by a practitioner must have two (2) signature lines
24 printed at the bottom of the prescription form, one (1) of which must
25 be signed by the practitioner for the prescription to be valid. Under the
26 blank line on the left side of the form must be printed the words
27 "Dispense as written.". Under the blank line on the right side of the
28 form must be printed the words "May substitute.".

29 **(b) Each electronically transmitted prescription issued by a**
30 **practitioner must:**

31 **(1) have an electronic signature; and**
32 **(2) include the electronically transmitted instructions**
33 **"Dispense as written." or "May substitute.".**

34 SECTION 11. IC 16-42-22-8 IS AMENDED TO READ AS
35 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 8. (a) For substitution
36 to occur for a prescription other than a prescription filled under the
37 Medicaid program (42 U.S.C. 1396 et seq.), the children's health
38 insurance program established under IC 12-17.6-2, or the Medicare
39 program (42 U.S.C. 1395 et seq.):

40 (1) the practitioner must:

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

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1 **(B) for an electronically transmitted prescription,**
 2 **electronically transmit the instruction "May substitute.";**
 3 and
 4 (2) the pharmacist must inform the customer of the substitution.
 5 (b) This section does not authorize any substitution other than
 6 substitution of a generically equivalent drug product.
 7 SECTION 12. IC 16-42-22-9 IS AMENDED TO READ AS
 8 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 9. If the practitioner
 9 communicates instructions to the pharmacist orally **or electronically,**
 10 the pharmacist shall:
 11 (1) indicate the instructions in the pharmacist's own handwriting
 12 on the written copy of the prescription order; **or**
 13 **(2) record the electronically transmitted instructions in an**
 14 **electronic format.**
 15 SECTION 13. IC 16-42-22-10 IS AMENDED TO READ AS
 16 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 10. (a) If a prescription
 17 is filled under the Medicaid program (42 U.S.C. 1396 et seq.), the
 18 children's health insurance program established under IC 12-17.6-2, or
 19 the Medicare program (42 U.S.C. 1395 et seq.), the pharmacist shall
 20 substitute a generically equivalent drug product and inform the
 21 customer of the substitution if the substitution would result in a lower
 22 price unless:
 23 (1) the words "Brand Medically Necessary" are:
 24 **(A) written in the practitioner's own writing on the form; or**
 25 **(B) electronically transmitted with an electronically**
 26 **transmitted prescription; or**
 27 (2) the practitioner has indicated that the pharmacist may not
 28 substitute a generically equivalent drug product by:
 29 **(A) orally stating that a substitution is not permitted; or**
 30 **(B) for an electronically transmitted prescription,**
 31 **indicating with the electronic prescription that a**
 32 **substitution is not permitted.**
 33 (b) If a practitioner orally states that a generically equivalent drug
 34 product may not be substituted, the practitioner must subsequently
 35 forward to the pharmacist a written **or electronically transmitted**
 36 prescription with the "Brand Medically Necessary" instruction
 37 appropriately indicated in the physician's own handwriting.
 38 (c) This section does not authorize any substitution other than
 39 substitution of a generically equivalent drug product.
 40 SECTION 14. IC 16-42-22-12 IS AMENDED TO READ AS
 41 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 12. The pharmacist
 42 shall record on the prescription **in writing or in an electronic format**

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1 **for an electronically transmitted prescription** the name of the
 2 manufacturer or distributor, or both, of the actual drug product
 3 dispensed under this chapter.

4 SECTION 15. IC 25-26-13-2 IS AMENDED TO READ AS
 5 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 2. As used in this
 6 chapter:

7 "Board" means the Indiana board of pharmacy.

8 "Controlled drugs" are those drugs on schedules I through V of the
 9 Federal Controlled Substances Act or on schedules I through V of
 10 IC 35-48-2.

11 "Counseling" means effective communication between a pharmacist
 12 and a patient concerning the contents, drug to drug interactions, route,
 13 dosage, form, directions for use, precautions, and effective use of a
 14 drug or device to improve the therapeutic outcome of the patient
 15 through the effective use of the drug or device.

16 "Dispensing" means issuing one (1) or more doses of a drug in a
 17 suitable container with appropriate labeling for subsequent
 18 administration to or use by a patient.

19 "Drug" means:

20 (1) articles or substances recognized in the official United States
 21 Pharmacopoeia, official National Formulary, official
 22 Homeopathic Pharmacopoeia of the United States, or any
 23 supplement to any of them;

24 (2) articles or substances intended for use in the diagnosis, cure,
 25 mitigation, treatment, or prevention of disease in man or animals;

26 (3) articles other than food intended to affect the structure or any
 27 function of the body of man or animals; or

28 (4) articles intended for use as a component of any article
 29 specified in subdivisions (1) through (3) and devices.

30 "Drug order" means a written order in a hospital or other health care
 31 institution for an ultimate user for any drug or device, issued and
 32 signed by a practitioner, or an order transmitted by other means of
 33 communication from a practitioner, which is immediately reduced to
 34 writing by the pharmacist, registered nurse, or other licensed health
 35 care practitioner authorized by the hospital or institution. The order
 36 shall contain the name and bed number of the patient; the name and
 37 strength or size of the drug or device; unless specified by individual
 38 institution policy or guideline, the amount to be dispensed either in
 39 quantity or days; adequate directions for the proper use of the drug or
 40 device when it is administered to the patient; and the name of the
 41 prescriber.

42 "Drug regimen review" means the retrospective, concurrent, and

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1 prospective review by a pharmacist of a patient's drug related history
2 that includes the following areas:

- 3 (1) Evaluation of prescriptions or drug orders and patient records
- 4 for drug allergies, rational therapy contradictions, appropriate
- 5 dose and route of administration, appropriate directions for use,
- 6 or duplicative therapies.
- 7 (2) Evaluation of prescriptions or drug orders and patient records
- 8 for drug-drug, drug-food, drug-disease, and drug-clinical
- 9 laboratory interactions.
- 10 (3) Evaluation of prescriptions or drug orders and patient records
- 11 for adverse drug reactions.
- 12 (4) Evaluation of prescriptions or drug orders and patient records
- 13 for proper utilization and optimal therapeutic outcomes.

14 "Drug utilization review" means a program designed to measure and
15 assess on a retrospective and prospective basis the proper use of drugs.

16 "Device" means an instrument, apparatus, implement, machine,
17 contrivance, implant, in vitro reagent, or other similar or related article
18 including any component part or accessory, which is:

- 19 (1) recognized in the official United States Pharmacopoeia,
- 20 official National Formulary, or any supplement to them;
- 21 (2) intended for use in the diagnosis of disease or other conditions
- 22 or the cure, mitigation, treatment, or prevention of disease in man
- 23 or other animals; or
- 24 (3) intended to affect the structure or any function of the body of
- 25 man or other animals and which does not achieve any of its
- 26 principal intended purposes through chemical action within or on
- 27 the body of man or other animals and which is not dependent
- 28 upon being metabolized for the achievement of any of its
- 29 principal intended purposes.

30 **"Electronic data intermediary" means an entity that provides**
31 **the infrastructure that connects a computer system or another**
32 **electronic device used by a prescribing practitioner with a**
33 **computer system or another electronic device used by a pharmacy**
34 **to facilitate the secure transmission of:**

- 35 (1) an electronic prescription order;
- 36 (2) a refill authorization request;
- 37 (3) a communication; and
- 38 (4) other patient care information;

39 between a practitioner and a pharmacy.

40 "Electronic signature" means an electronic sound, symbol, or
41 process:

- 42 (1) attached to or logically associated with a record; and

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**(2) executed or adopted by a person;
with the intent to sign the record.**

"Electronically transmitted" or "electronic transmission" means the transmission of a prescription in electronic form. The term does not include the transmission of a prescription by facsimile.

"Investigational or new drug" means any drug which is limited by state or federal law to use under professional supervision of a practitioner authorized by law to prescribe or administer such drug.

"Legend drug" has the meaning set forth in IC 16-18-2-199.

"License" and "permit" are interchangeable and mean a written certificate from the Indiana board of pharmacy for the practice of pharmacy or the operation of a pharmacy.

"Nonprescription drug" means a drug that may be sold without a prescription and that is labeled for use by a patient in accordance with state and federal laws.

"Person" means any individual, partnership, copartnership, firm, company, corporation, association, joint stock company, trust, estate, or municipality, or a legal representative or agent, unless this chapter expressly provides otherwise.

"Practitioner" has the meaning set forth in IC 16-42-19-5.

"Pharmacist" means a person licensed under this chapter.

"Pharmacist extern" means a pharmacy student enrolled full time in an approved school of pharmacy and who is working in a school sponsored, board approved program related to the practice of pharmacy.

"Pharmacist intern" means a person who is working to secure additional hours of practice and experience prior to making application for a license to practice as a pharmacist.

"Pharmacy" means any facility, department, or other place where prescriptions are filled or compounded and are sold, dispensed, offered, or displayed for sale and which has as its principal purpose the dispensing of drug and health supplies intended for the general health, welfare, and safety of the public, without placing any other activity on a more important level than the practice of pharmacy.

"The practice of pharmacy" or "the practice of the profession of pharmacy" means a patient oriented health care profession in which pharmacists interact with and counsel patients and with other health care professionals concerning drugs and devices used to enhance patients' wellness, prevent illness, and optimize the outcome of a drug or device, by accepting responsibility for performing or supervising a pharmacist intern, a pharmacist extern, or an unlicensed person under

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1 section 18(a)(4) of this chapter to do the following acts, services, and
2 operations:

3 (1) The offering of or performing of those acts, service operations,
4 or transactions incidental to the interpretation, evaluation, and
5 implementation of prescriptions or drug orders.

6 (2) The compounding, labeling, administering, dispensing, or
7 selling of drugs and devices, including radioactive substances,
8 whether dispensed under a practitioner's prescription or drug
9 order or sold or given directly to the ultimate consumer.

10 (3) The proper and safe storage and distribution of drugs and
11 devices.

12 (4) The maintenance of proper records of the receipt, storage,
13 sale, and dispensing of drugs and devices.

14 (5) Counseling, advising, and educating patients, patients'
15 caregivers, and health care providers and professionals, as
16 necessary, as to the contents, therapeutic values, uses, significant
17 problems, risks, and appropriate manner of use of drugs and
18 devices.

19 (6) Assessing, recording, and reporting events related to the use
20 of drugs or devices.

21 (7) Provision of the professional acts, professional decisions, and
22 professional services necessary to maintain all areas of a patient's
23 pharmacy related care as specifically authorized to a pharmacist
24 under this article.

25 "Prescription" means a written order or an order transmitted by other
26 means of communication from a practitioner to or for an ultimate user
27 for any drug or device containing the name and address of the patient,
28 the name and strength or size of the drug or device, the amount to be
29 dispensed; adequate directions for the proper use of the drug or device
30 by the patient; and the name of the practitioner issued and; if the
31 prescription is in written form; signed by a practitioner.

32 "Prescription" means a written order or an order transmitted by other
33 means of communication from a practitioner to or for an ultimate user
34 for any drug or device containing:

35 (1) the name and address of the patient;

36 (2) the date of issue;

37 (3) the name and strength or size (if applicable) of the drug or
38 device;

39 (4) the amount to be dispensed (unless indicated by directions and
40 duration of therapy);

41 (5) adequate directions for the proper use of the drug or device by
42 the patient;

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- 1 (6) the name of the practitioner; and
- 2 (7) ~~the signature of the practitioner~~ if the prescription:
- 3 (A) is in written form, **the signature of the practitioner; or**
- 4 **(B) is in electronic form, the electronic signature of the**
- 5 **practitioner.**
- 6 "Qualifying pharmacist" means the pharmacist who will qualify the
- 7 pharmacy by being responsible to the board for the legal operations of
- 8 the pharmacy under the permit.
- 9 "Record" means all papers, letters, memoranda, notes, prescriptions,
- 10 drug orders, invoices, statements, patient medication charts or files,
- 11 computerized records, or other written indicia, documents, or objects
- 12 which are used in any way in connection with the purchase, sale, or
- 13 handling of any drug or device.
- 14 "Sale" means every sale and includes:
- 15 (1) manufacturing, processing, transporting, handling, packaging,
- 16 or any other production, preparation, or repackaging;
- 17 (2) exposure, offer, or any other proffer;
- 18 (3) holding, storing, or any other possession;
- 19 (4) dispensing, giving, delivering, or any other supplying; and
- 20 (5) applying, administering, or any other using.
- 21 SECTION 16. IC 25-26-13-4 IS AMENDED TO READ AS
- 22 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 4. (a) The board may:
- 23 (1) promulgate rules and regulations under IC 4-22-2 for
- 24 implementing and enforcing this chapter;
- 25 (2) establish requirements and tests to determine the moral,
- 26 physical, intellectual, educational, scientific, technical, and
- 27 professional qualifications for applicants for pharmacists'
- 28 licenses;
- 29 (3) refuse to issue, deny, suspend, or revoke a license or permit or
- 30 place on probation or fine any licensee or permittee under this
- 31 chapter;
- 32 (4) regulate the sale of drugs and devices in the state of Indiana;
- 33 (5) impound, embargo, confiscate, or otherwise prevent from
- 34 disposition any drugs, medicines, chemicals, poisons, or devices
- 35 which by inspection are deemed unfit for use or would be
- 36 dangerous to the health and welfare of the citizens of the state of
- 37 Indiana; the board shall follow those embargo procedures found
- 38 in IC 16-42-1-18 through IC 16-42-1-31, and persons may not
- 39 refuse to permit or otherwise prevent members of the board or
- 40 their representatives from entering such places and making such
- 41 inspections;
- 42 (6) prescribe minimum standards with respect to physical

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1 characteristics of pharmacies, as may be necessary to the
 2 maintenance of professional surroundings and to the protection of
 3 the safety and welfare of the public;
 4 (7) subject to IC 25-1-7, investigate complaints, subpoena
 5 witnesses, schedule and conduct hearings on behalf of the public
 6 interest on any matter under the jurisdiction of the board;
 7 (8) prescribe the time, place, method, manner, scope, and subjects
 8 of licensing examinations which shall be given at least twice
 9 annually; and
 10 (9) perform such other duties and functions and exercise such
 11 other powers as may be necessary to implement and enforce this
 12 chapter.
 13 (b) The board shall adopt rules under IC 4-22-2 for the following:
 14 (1) Establishing standards for the competent practice of
 15 pharmacy.
 16 (2) Establishing the standards for a pharmacist to counsel
 17 individuals regarding the proper use of drugs.
 18 (c) The board may grant or deny a temporary variance to a rule it
 19 has adopted if:
 20 (1) the board has adopted rules which set forth the procedures and
 21 standards governing the grant or denial of a temporary variance;
 22 and
 23 (2) the board sets forth in writing the reasons for a grant or denial
 24 of a temporary variance.
 25 **(d) The board shall adopt rules and procedures, in consultation**
 26 **with the medical licensing board, concerning the electronic**
 27 **transmission of prescriptions. The rules adopted under this**
 28 **subsection must address the following:**
 29 **(1) Privacy protection for the practitioner and the**
 30 **practitioner's patient.**
 31 **(2) Security of the electronic transmission.**
 32 **(3) A process for approving electronic data intermediaries for**
 33 **the electronic transmission of prescriptions.**
 34 **(4) Use of a practitioner's United States Drug Enforcement**
 35 **Agency registration number.**
 36 **(5) Protection of the practitioner from identity theft or**
 37 **fraudulent use of the practitioner's prescribing authority.**
 38 SECTION 17. IC 25-26-13-25 IS AMENDED TO READ AS
 39 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 25. (a) All original
 40 prescriptions, whether in written or electronic format, shall be
 41 numbered and maintained in numerical and chronological order, or in
 42 a manner approved by the board and accessible for at least two (2)

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1 years in the pharmacy. A prescription transmitted from a practitioner
2 by means of communication other than writing must immediately be
3 reduced to writing or recorded in an electronic format by the
4 pharmacist. The files shall be open for inspection to any member of the
5 board or its duly authorized agent or representative.

6 **(b) A prescription may be electronically transmitted from the**
7 **practitioner by computer or another electronic device to a**
8 **pharmacy that is licensed under this article or any other state or**
9 **territory. An electronic data intermediary that is approved by the**
10 **board:**

- 11 (1) **may transmit the prescription information between the**
- 12 **prescribing practitioner and the pharmacy;**
- 13 (2) **may archive copies of the electronic information related to**
- 14 **the transmissions as necessary for auditing and security**
- 15 **purposes; and**
- 16 (3) **must maintain patient privacy and confidentiality of all**
- 17 **archived information as required by applicable state and**
- 18 **federal laws.**

19 ~~(b)~~ **(c)** Except as provided in subsection ~~(c)~~; **(d)**, a prescription for
20 any drug, the label of which bears either the legend, "Caution: Federal
21 law prohibits dispensing without prescription" or "Rx Only", may not
22 be refilled without written, **electronically transmitted**, or oral
23 authorization of a licensed practitioner.

24 ~~(c)~~ **(d)** A prescription for any drug, the label of which bears either
25 the legend, "Caution: Federal law prohibits dispensing without
26 prescription" or "Rx Only", may be refilled by a pharmacist one (1)
27 time without the written, **electronically transmitted**, or oral
28 authorization of a licensed practitioner if all of the following conditions
29 are met:

- 30 (1) The pharmacist has made every reasonable effort to contact
- 31 the original prescribing practitioner or the practitioner's designee
- 32 for consultation and authorization of the prescription refill.
- 33 (2) The pharmacist believes that, under the circumstances, failure
- 34 to provide a refill would be seriously detrimental to the patient's
- 35 health.
- 36 (3) The original prescription authorized a refill but a refill would
- 37 otherwise be invalid for either of the following reasons:
- 38 (A) All of the authorized refills have been dispensed.
- 39 (B) The prescription has expired under subsection ~~(f)~~; **(g)**.
- 40 (4) The prescription for which the patient requests the refill was:
- 41 (A) originally filled at the pharmacy where the request for a
- 42 refill is received and the prescription has not been transferred

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- 1 for refills to another pharmacy at any time; or
- 2 (B) filled at or transferred to another location of the same
- 3 pharmacy or its affiliate owned by the same parent corporation
- 4 if the pharmacy filling the prescription has full access to
- 5 prescription and patient profile information that is
- 6 simultaneously and continuously updated on the parent
- 7 corporation's information system.
- 8 (5) The drug is prescribed for continuous and uninterrupted use
- 9 and the pharmacist determines that the drug is being taken
- 10 properly in accordance with IC 25-26-16.
- 11 (6) The pharmacist shall document the following information
- 12 regarding the refill:
- 13 (A) The information required for any refill dispensed under
- 14 subsection ~~(d)~~: **(e)**.
- 15 (B) The dates and times that the pharmacist attempted to
- 16 contact the prescribing practitioner or the practitioner's
- 17 designee for consultation and authorization of the prescription
- 18 refill.
- 19 (C) The fact that the pharmacist dispensed the refill without
- 20 the authorization of a licensed practitioner.
- 21 (7) The pharmacist notifies the original prescribing practitioner
- 22 of the refill and the reason for the refill by the practitioner's next
- 23 business day after the refill has been made by the pharmacist.
- 24 (8) Any pharmacist initiated refill under this subsection may not
- 25 be for more than the minimum amount necessary to supply the
- 26 patient through the prescribing practitioner's next business day.
- 27 However, a pharmacist may dispense a drug in an amount greater
- 28 than the minimum amount necessary to supply the patient through
- 29 the prescribing practitioner's next business day if:
- 30 (A) the drug is packaged in a form that requires the pharmacist
- 31 to dispense the drug in a quantity greater than the minimum
- 32 amount necessary to supply the patient through the prescribing
- 33 practitioner's next business day; or
- 34 (B) the pharmacist documents in the patient's record the
- 35 amount of the drug dispensed and a compelling reason for
- 36 dispensing the drug in a quantity greater than the minimum
- 37 amount necessary to supply the patient through the prescribing
- 38 practitioner's next business day.
- 39 (9) Not more than one (1) pharmacist initiated refill is dispensed
- 40 under this subsection for a single prescription.
- 41 (10) The drug prescribed is not a controlled substance.
- 42 A pharmacist may not refill a prescription under this subsection if the

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- 1 practitioner has designated on the prescription form the words "No
- 2 Emergency Refill".
- 3 ~~(d)~~ (e) When refilling a prescription, the refill record shall include:
- 4 (1) the date of the refill;
- 5 (2) the quantity dispensed if other than the original quantity; and
- 6 (3) the dispenser's identity on:
- 7 (A) the original prescription form; or
- 8 (B) another board approved, uniformly maintained, readily
- 9 retrievable record.
- 10 ~~(e)~~ (f) The original prescription form or the other board approved
- 11 record described in subsection ~~(d)~~ (e) must indicate by the number of
- 12 the original prescription the following information:
- 13 (1) The name and dosage form of the drug.
- 14 (2) The date of each refill.
- 15 (3) The quantity dispensed.
- 16 (4) The identity of the pharmacist who dispensed the refill.
- 17 (5) The total number of refills for that prescription.
- 18 ~~(f)~~ (g) A prescription is valid for not more than one (1) year after the
- 19 original date of issue.
- 20 ~~(g)~~ (h) A pharmacist may not knowingly dispense a prescription
- 21 after the demise of the practitioner, unless in the pharmacist's
- 22 professional judgment it is in the best interest of the patient's health.
- 23 ~~(h)~~ (i) A pharmacist may not knowingly dispense a prescription after
- 24 the demise of the patient.
- 25 ~~(i)~~ (j) A pharmacist or a pharmacy shall not resell, reuse, or
- 26 redistribute a medication that is returned to the pharmacy after being
- 27 dispensed unless the medication:
- 28 (1) was dispensed to a patient:
- 29 (A) residing in an institutional facility (as defined in 856
- 30 IAC 1-28.1-1(6)); or
- 31 (B) in a hospice program under IC 16-25;
- 32 (2) was properly stored and securely maintained according to
- 33 sound pharmacy practices;
- 34 (3) is returned unopened and:
- 35 (A) was dispensed in the manufacturer's original:
- 36 (i) bulk, multiple dose container with an unbroken tamper
- 37 resistant seal; or
- 38 (ii) unit dose package; or
- 39 (B) was packaged by the dispensing pharmacy in a:
- 40 (i) multiple dose blister container; or
- 41 (ii) unit dose package;
- 42 (4) was dispensed by the same pharmacy as the pharmacy

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1 accepting the return;
 2 (5) is not expired; and
 3 (6) is not a controlled substance (as defined in IC 35-48-1-9),
 4 unless the pharmacy holds a Type II permit (as described in
 5 section 17 of this chapter).

6 ~~(j)~~ **(k)** A pharmacist may use the pharmacist's professional judgment
 7 as to whether to accept medication for return under this section.

8 ~~(k)~~ **(l)** A pharmacist who violates subsection ~~(c)~~ **(d)** commits a Class
 9 A infraction.

10 SECTION 18. IC 25-26-13-25.5 IS ADDED TO THE INDIANA
 11 CODE AS A NEW SECTION TO READ AS FOLLOWS
 12 [EFFECTIVE JULY 1, 2005]: **Sec. 25.5. A prescription may be**
 13 **transmitted electronically from a practitioner to a pharmacy only**
 14 **through the use of an electronic data intermediary approved by the**
 15 **board.**

16 SECTION 19. IC 25-26-14-1 IS AMENDED TO READ AS
 17 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 1. **(a)** This chapter
 18 applies to any individual, partnership, limited liability company,
 19 corporation, or business firm:

- 20 **(1) located within or outside Indiana; and**
- 21 **(2) engaging in the wholesale distribution of legend drugs within**
 22 **in Indiana.**

23 **(b) Except as required by federal law or regulation, the**
 24 **requirements of this chapter do not apply to a manufacturer that**
 25 **is approved by the federal Food and Drug Administration.**
 26 **However, the board may adopt rules concerning manufacturers**
 27 **that the board considers appropriate and necessary.**

28 SECTION 20. IC 25-26-14-1.5 IS ADDED TO THE INDIANA
 29 CODE AS A NEW SECTION TO READ AS FOLLOWS
 30 [EFFECTIVE JULY 1, 2005]: **Sec. 1.5. As used in this chapter,**
 31 **"adulterated" refers to a drug that:**

- 32 **(1) consists in whole or in part of a filthy, putrid, or**
 33 **decomposed substance;**
- 34 **(2) has been produced, prepared, packed, or held under**
 35 **unsanitary conditions and may have been contaminated or**
 36 **rendered injurious to health;**
- 37 **(3) has been subjected to conditions in the manufacture,**
 38 **processing, packing, or holding of the drug that do not**
 39 **conform to current standards of manufacturing to ensure that**
 40 **the drug is safe for use and possesses the identity, strength,**
 41 **quality, and purity characteristics that the drug is represented**
 42 **to possess;**

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- 1 **(4) is contained in a container composed of a poisonous or**
- 2 **deleterious substance that may render the drug injurious to**
- 3 **health;**
- 4 **(5) bears or contains, for purposes of coloring only, a color**
- 5 **additive that is unsafe;**
- 6 **(6) is of a different strength, quality, or purity from the**
- 7 **official compendium standard for the drug; or**
- 8 **(7) does not meet the considerations of the federal Food, Drug,**
- 9 **and Cosmetic Act.**

10 SECTION 21. IC 25-26-14-1.7 IS ADDED TO THE INDIANA
 11 CODE AS A NEW SECTION TO READ AS FOLLOWS
 12 [EFFECTIVE JULY 1, 2005]: **Sec. 1.7. As used in this chapter,**
 13 **"authenticate" means to affirmatively verify before distribution**
 14 **occurs that each transaction that is listed on:**

- 15 **(1) the pedigree of a drug; and**
- 16 **(2) other accompanying documentation for a drug;**
- 17 **has occurred.**

18 SECTION 22. IC 25-26-14-1.8 IS ADDED TO THE INDIANA
 19 CODE AS A NEW SECTION TO READ AS FOLLOWS
 20 [EFFECTIVE JULY 1, 2005]: **Sec. 1.8. As used in this chapter,**
 21 **"authorized distributor" means a wholesale drug distributor with**
 22 **which a manufacturer has established an ongoing relationship to**
 23 **distribute the manufacturer's products. For purposes of this**
 24 **section, an ongoing relationship exists between a wholesale drug**
 25 **distributor, including any affiliated group (as defined in Section**
 26 **1504 of the Internal Revenue Code) of which the wholesale**
 27 **distributor is a member, and a manufacturer if the wholesale drug**
 28 **distributor:**

- 29 **(1) has a written agreement currently in effect with the**
- 30 **manufacturer evidencing an ongoing relationship;**
- 31 **(2) is listed on the manufacturer's current monthly updated**
- 32 **list of authorized distributors; or**
- 33 **(3) has a verifiable account with the manufacturer and a**
- 34 **minimal transaction or volume requirement limit of:**
- 35 **(A) five thousand (5,000) units per company in the**
- 36 **previous twelve (12) months; or**
- 37 **(B) twelve (12) purchases at the manufacturer's minimum**
- 38 **purchasing requirement per invoice in the previous twelve**
- 39 **(12) months.**

40 SECTION 23. IC 25-26-14-4.1 IS ADDED TO THE INDIANA
 41 CODE AS A NEW SECTION TO READ AS FOLLOWS
 42 [EFFECTIVE JULY 1, 2005]: **Sec. 4.1. As used in this chapter,**

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- 1 **"compendium" refers to:**
 2 (1) the United States Pharmacopoeia;
 3 (2) the Homeopathic Pharmacopoeia of the United States;
 4 (3) the National Formulary;
 5 (4) a drug approved by the federal Food and Drug
 6 Administration; or
 7 (5) a supplement to a document specified in subdivision (1),
 8 (2), or (3).

9 SECTION 24. IC 25-26-14-4.2 IS ADDED TO THE INDIANA
 10 CODE AS A NEW SECTION TO READ AS FOLLOWS
 11 [EFFECTIVE JULY 1, 2005]: **Sec. 4.2. As used in this chapter,**
 12 **"contraband" refers to a drug:**

- 13 (1) that is counterfeit;
 14 (2) that is stolen;
 15 (3) that is misbranded;
 16 (4) that is obtained by fraud;
 17 (5) that is purchased by a nonprofit institution for the
 18 nonprofit institution's own use and placed in commerce in
 19 violation of the own use agreement for the drug;
 20 (6) for which a required pedigree does not exist; or
 21 (7) for which a pedigree in existence:
 22 (A) has been forged, counterfeited, or falsely created; or
 23 (B) contains any altered, false, or misrepresented
 24 information.

25 SECTION 25. IC 25-26-14-4.3 IS ADDED TO THE INDIANA
 26 CODE AS A NEW SECTION TO READ AS FOLLOWS
 27 [EFFECTIVE JULY 1, 2005]: **Sec. 4.3. As used in this chapter,**
 28 **"counterfeit" refers to a drug, or the container, seal, or labeling of**
 29 **a drug, that, without authorization, bears the trademark, trade**
 30 **name, or other identifying mark or imprint of a manufacturer,**
 31 **processor, packer, or distributor other than the person that**
 32 **manufactured, processed, packed, or distributed the drug.**

33 SECTION 26. IC 25-26-14-4.4 IS ADDED TO THE INDIANA
 34 CODE AS A NEW SECTION TO READ AS FOLLOWS
 35 [EFFECTIVE JULY 1, 2005]: **Sec. 4.4. As used in this chapter,**
 36 **"deliver" means the actual, constructive, or attempted transfer of**
 37 **a drug from one (1) person to another.**

38 SECTION 27. IC 25-26-14-4.5 IS ADDED TO THE INDIANA
 39 CODE AS A NEW SECTION TO READ AS FOLLOWS
 40 [EFFECTIVE JULY 1, 2005]: **Sec. 4.5. As used in this chapter,**
 41 **"designated representative" means an individual who:**
 42 (1) is designated by a wholesale drug distributor;

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- 1 **(2) serves as the wholesale drug distributor's responsible**
- 2 **individual with the board; and**
- 3 **(3) is actively involved in and aware of the actual daily**
- 4 **operation of the wholesale drug distributor.**

5 SECTION 28. IC 25-26-14-4.7 IS ADDED TO THE INDIANA
 6 CODE AS A NEW SECTION TO READ AS FOLLOWS
 7 [EFFECTIVE JULY 1, 2005]: **Sec. 4.7. As used in this chapter,**
 8 **"distribute" means to sell, offer to sell, deliver, offer to deliver,**
 9 **broker, give away, or transfer a legend drug, whether by passage**
 10 **of title or physical movement, or both. The term does not include**
 11 **the following:**

- 12 **(1) Dispensing or administering a legend drug.**
- 13 **(2) Delivering or offering to deliver a legend drug by a**
- 14 **common carrier in the usual course of business as a common**
- 15 **carrier.**
- 16 **(3) The provision of a drug sample to a patient by a:**
- 17 **(A) practitioner;**
- 18 **(B) health care professional acting at the direction and**
- 19 **under the supervision of a practitioner; or**
- 20 **(C) hospital's or other health care entity's pharmacy that**
- 21 **received the drug sample in accordance with this chapter**
- 22 **and other applicable law to administer or dispense and**
- 23 **that is acting at the direction of a practitioner;**
- 24 **licensed to prescribe the legend drug.**

25 SECTION 29. IC 25-26-14-4.9 IS ADDED TO THE INDIANA
 26 CODE AS A NEW SECTION TO READ AS FOLLOWS
 27 [EFFECTIVE JULY 1, 2005]: **Sec. 4.9. As used in this chapter,**
 28 **"drug" means any of the following:**

- 29 **(1) Articles recognized in an official compendium and**
- 30 **designated by the board for use in the diagnosis, cure,**
- 31 **mitigation, treatment, or prevention of disease in humans or**
- 32 **animals.**
- 33 **(2) Articles intended for use in the diagnosis, cure, mitigation,**
- 34 **treatment, or prevention of disease in humans or animals.**
- 35 **(3) Articles other than food intended to affect the structure or**
- 36 **function of the body of humans or animals.**
- 37 **(4) Articles intended for use as a component of an article**
- 38 **specified in subdivision (1), (2), or (3).**

39 **The term does not include a device or a device component, part, or**
 40 **accessory.**

41 SECTION 30. IC 25-26-14-6 IS AMENDED TO READ AS
 42 FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 6. As used in this**

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1 chapter, "health care entity" means any organization or business that
 2 provides diagnostic, medical, surgical, dental treatment, or
 3 rehabilitative care. **The term does not include a pharmacy or**
 4 **wholesale drug distributor.**

5 SECTION 31. IC 25-26-14-6.5 IS ADDED TO THE INDIANA
 6 CODE AS A NEW SECTION TO READ AS FOLLOWS
 7 [EFFECTIVE JULY 1, 2005]: **Sec. 6.5. As used in this chapter,**
 8 **"label" means a display of written, printed, or graphic matter on**
 9 **the immediate container of a legend drug.**

10 SECTION 32. IC 25-26-14-6.6 IS ADDED TO THE INDIANA
 11 CODE AS A NEW SECTION TO READ AS FOLLOWS
 12 [EFFECTIVE JULY 1, 2005]: **Sec. 6.6. As used in this chapter,**
 13 **"labeling" means labels and other written, printed, or graphic**
 14 **matter:**

- 15 (1) on a legend drug or a legend drug's container or wrapper;
 16 or
 17 (2) accompanying a legend drug.

18 SECTION 33. IC 25-26-14-8.3 IS ADDED TO THE INDIANA
 19 CODE AS A NEW SECTION TO READ AS FOLLOWS
 20 [EFFECTIVE JULY 1, 2005]: **Sec. 8.3. As used in this chapter,**
 21 **"misbranded" means that a legend drug's label:**

- 22 (1) is false or misleading;
 23 (2) does not bear the name and address of the manufacturer,
 24 packer, or distributor or does not contain an accurate
 25 statement of the quantities of active ingredients of the legend
 26 drug;
 27 (3) does not show an accurate monograph for the legend drug;
 28 or
 29 (4) does not comply with any other requirements of the
 30 federal Food, Drug and Cosmetic Act.

31 SECTION 34. IC 25-26-14-8.7 IS ADDED TO THE INDIANA
 32 CODE AS A NEW SECTION TO READ AS FOLLOWS
 33 [EFFECTIVE JULY 1, 2005]: **Sec. 8.7. As used in this chapter,**
 34 **"pedigree" means a statement or record in a written or an**
 35 **electronic form that is approved by the board, that records each**
 36 **distribution of a legend drug from the sale by the manufacturer or,**
 37 **except for drugs on the specified list of susceptible products, from**
 38 **the last authorized distributor of record through acquisition and**
 39 **sale by each wholesale drug distributor, and that includes the**
 40 **following information for each transaction:**

- 41 (1) The source of the legend drug, including the name and
 42 principal address of the seller.

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- 1 **(2) The:**
 2 **(A) amount and dosage form and strength;**
 3 **(B) date of purchase;**
 4 **(C) sales invoice number;**
 5 **(D) container size;**
 6 **(E) number of containers;**
 7 **(F) lot number; and**
 8 **(G) proprietary and established name;**
 9 **of the legend drug.**
- 10 **(3) The:**
 11 **(A) business name and address of each owner of the legend**
 12 **drug; and**
 13 **(B) legend drug's shipping information, including the name**
 14 **and address of the facility of each person certifying**
 15 **delivery or receipt of the legend drug.**
- 16 **(4) Information that states that the wholesale drug distributor**
 17 **has acted with due diligence as required under this chapter**
 18 **with respect to another wholesale drug distributor from**
 19 **which the wholesale drug distributor purchased or may have**
 20 **purchased the legend drug.**
- 21 **(5) A certification from the designated representative of the**
 22 **wholesale drug distributor that the information contained in**
 23 **the document is true and accurate under penalty of perjury.**
- 24 SECTION 35. IC 25-26-14-9 IS AMENDED TO READ AS
 25 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 9. As used in this
 26 chapter, "person" means an individual, a partnership, a business firm,
 27 a limited liability company, ~~or~~ a corporation, **or another entity,**
 28 **including a governmental entity.**
- 29 SECTION 36. IC 25-26-14-9.2 IS ADDED TO THE INDIANA
 30 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
 31 [EFFECTIVE JULY 1, 2005]: **Sec. 9.2. As used in this chapter,**
 32 **"practitioner" has the meaning set forth in IC 16-42-19-5.**
- 33 SECTION 37. IC 25-26-14-9.3 IS ADDED TO THE INDIANA
 34 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
 35 [EFFECTIVE JULY 1, 2005]: **Sec. 9.3. As used in this chapter,**
 36 **"repackage" means changing the container, wrapper, quantity, or**
 37 **labeling of a legend drug to further the distribution of the legend**
 38 **drug.**
- 39 SECTION 38. IC 25-26-14-10.5 IS ADDED TO THE INDIANA
 40 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
 41 [EFFECTIVE JULY 1, 2005]: **Sec. 10.5. As used in this chapter,**
 42 **"specified list of susceptible products" means a specific list of**

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1 **legend drugs established by the board, the board's agent, or a third**
2 **party approved by the board, as:**

3 **(1) susceptible to adulteration, counterfeiting, or diversion;**
4 **and**

5 **(2) posing the potential for a particular public health risk.**

6 SECTION 39. IC 25-26-14-11 IS AMENDED TO READ AS
7 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 11. As used in this
8 chapter, "wholesale distribution" means ~~distribution of~~ **to distribute**
9 legend drugs to persons other than a consumer or patient. The term
10 does not include:

11 (1) a sale **or transfer** between a division, a subsidiary, a parent,
12 an affiliated, or a related company under the common ownership
13 and control of a corporate entity;

14 (2) the purchase or acquisition by a hospital or other health care
15 entity that is a member of a group purchasing organization of a
16 drug for the hospital's or health care entity's own use from the
17 group purchasing organization or from other hospitals or health
18 care entities that are members of the organization;

19 (3) the sale of a drug by a charitable organization described in
20 Section 501(c)(3) of the Internal Revenue Code, to a nonprofit
21 affiliate of the organization to the extent otherwise permitted by
22 law;

23 (4) the sale of a drug among hospitals or other health care entities
24 that are under common control;

25 (5) the sale of a drug for emergency medical reasons, including
26 transfers of legend drugs by a retail pharmacy to another retail
27 pharmacy to alleviate a temporary shortage, if the gross dollar
28 value of the transfers does not exceed five percent (5%) of the
29 total legend drug sales revenue of either the transferor or
30 transferee pharmacy during any twelve (12) consecutive month
31 period;

32 (6) the sale of a drug or the dispensing of a drug pursuant to a
33 prescription;

34 (7) the distribution of drug samples by manufacturers'
35 representatives or distributors' representatives;

36 (8) the sale of blood and blood components intended for
37 transfusion;

38 (9) the sale of a drug by a retail pharmacy to a practitioner (as
39 defined in IC 25-26-13-2) for office use, if the gross dollar value
40 of the transfers does not exceed five percent (5%) of the retail
41 pharmacy's total legend drug sales during any twelve (12)
42 consecutive months; ⚔

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1 (10) the sale of a drug by a retail pharmacy that is ending its
 2 business and liquidating its inventory to another retail pharmacy;
 3 **(11) drug returns by a hospital, health care entity, or**
 4 **charitable institution conducted under 21 CFR 203.23;**
 5 **(12) the sale of minimal quantities of drugs by retail**
 6 **pharmacies to licensed practitioners for office use; or**
 7 **(13) the distribution of prescription drugs by the original**
 8 **manufacturer of the finished form of the prescription drug or**
 9 **the distribution of the prescription drugs by a co-promoting**
 10 **partner of the original manufacturer of the finished form of**
 11 **the prescription drug.**

12 SECTION 40. IC 25-26-14-12 IS AMENDED TO READ AS
 13 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 12. As used in this
 14 chapter, "wholesale drug distributor" means a person engaged in
 15 wholesale distribution of legend drugs, including:

- 16 (1) manufacturers;
 17 (2) repackers;
 18 (3) own-label distributors;
 19 (4) private-label distributors;
 20 (5) jobbers;
 21 (6) brokers;
 22 (7) warehouses, including manufacturers' and distributors'
 23 warehouses, chain drug warehouses, and wholesale drug
 24 warehouses;
 25 (8) independent wholesale drug traders; and
 26 (9) retail and hospital pharmacies that conduct wholesale
 27 distributions.

28 The term does not include a common carrier or person hired solely to
 29 transport prescription drugs.

30 SECTION 41. IC 25-26-14-14 IS AMENDED TO READ AS
 31 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 14. (a) ~~After September~~
 32 ~~14, 1992~~, A person may not engage in wholesale distributions of legend
 33 drugs without: ~~having~~

- 34 **(1) obtaining and maintaining accreditation or certification**
 35 **from an accreditation body approved by the board under**
 36 **subsection (g);**
 37 **(2) obtaining and maintaining** a license ~~from~~ **issued by the**
 38 **board; and**
 39 **(3) paying any reasonable fee required by the board.**

40 (b) The board may not issue or renew the license of a wholesale
 41 drug distributor that does not comply with this chapter.

42 (c) The board ~~may~~ **shall** require a separate license for

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1 (1) each facility directly or indirectly owned or operated by the
2 same business in Indiana; or

3 (2) a parent entity with divisions, subsidiaries, or affiliate
4 companies in Indiana when operations are conducted at more than
5 one (1) location and there exists joint ownership and control
6 among all the entities. or location where wholesale distribution
7 operations are conducted.

8 (d) An agent or employee of any licensed wholesale drug distributor
9 does not need a license and may lawfully possess pharmaceutical drugs
10 when acting in the usual course of business or employment.

11 (e) The issuance of a license under this chapter does not affect tax
12 liability imposed by the department of state revenue or the department
13 of local government finance on any wholesale drug distributor.

14 (f) The board may adopt rules that permit out-of-state wholesale
15 drug distributors to obtain a license on the basis of reciprocity if:

16 (1) an out-of-state wholesale drug distributor possesses a valid
17 license granted by another state and the legal standards for
18 licensure in the other state are comparable to the standards under
19 this chapter; and

20 (2) the other state extends reciprocity to wholesale drug
21 distributors licensed in Indiana.

22 **However, if the requirements for licensure under this chapter are**
23 **more restrictive than the standards of the other state, the**
24 **out-of-state wholesale drug distributor must comply with the**
25 **additional requirements of this chapter to obtain a license under**
26 **this chapter.**

27 (g) The board shall adopt rules under IC 4-22-2 to approve an
28 accreditation body to:

29 (1) evaluate a wholesale drug distributor's operations to
30 determine compliance with:

31 (A) professional standards;

32 (B) this chapter; and

33 (C) any other applicable law; and

34 (2) perform inspections of each facility and location where
35 wholesale distribution operations are conducted by the
36 wholesale drug distributor.

37 SECTION 42. IC 25-26-14-14.5 IS ADDED TO THE INDIANA
38 CODE AS A NEW SECTION TO READ AS FOLLOWS
39 [EFFECTIVE JULY 1, 2005]: **Sec. 14.5. After June 30, 2006, a**
40 **wholesale drug distributor may not accept or deliver a legend drug**
41 **without a current, accompanying pedigree.**

42 SECTION 43. IC 25-26-14-15 IS AMENDED TO READ AS

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1 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 15. (a) The board shall
 2 require the following minimum information from each wholesale drug
 3 distributor as part of the license described in section 14 of this chapter
 4 and as part of any renewal of such license:

5 (1) The name, full business address, and telephone number of the
 6 licensee.

7 (2) All trade or business names used by the licensee.

8 (3) Addresses, telephone numbers, and the names of contact
 9 persons for all facilities used by the licensee for the storage,
 10 handling, and distribution of legend drugs.

11 (4) The type of ownership of operation.

12 (5) The name of each owner and operator of the licensee,
 13 including:

14 (A) if an individual, the name, **address, Social Security**
 15 **number, and date of birth** of the individual;

16 (B) if a partnership, the name, **address, Social Security**
 17 **number, and date of birth** of each partner, and the name of
 18 the partnership **and federal employer identification number;**

19 (C) if a corporation:

20 (i) the name, **address, Social Security number, date of**
 21 **birth,** and title of each corporate officer and director;

22 (ii) the corporate names, ~~and~~ the name of the state of
 23 incorporation, **the federal employer identification**
 24 **number, and the name of the parent company, if any;**
 25 **and**

26 (iii) **the name, address, and Social Security number of**
 27 **each shareholder owning ten percent (10%) or more of**
 28 **the voting stock of the corporation, unless the stock is**
 29 **traded on a major stock exchange and not traded over**
 30 **the counter;**

31 (D) if a limited liability company, the name of each manager
 32 and member, the name **and federal identification number** of
 33 the limited liability company, and the name of the state where
 34 organized; and

35 (E) if a sole proprietorship, the full name, **address, Social**
 36 **Security number, and date of birth** of the sole proprietor and
 37 the name **and federal employer identification number** of the
 38 business entity.

39 (6) The name, **address, and telephone number** of the person
 40 designated by the licensee as responsible for the operation
 41 **representative of the facilities.** ~~each facility.~~

42 (7) **Additional information concerning record keeping**

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1 required under this chapter.

2 (b) The board shall require a wholesale drug distributor to post
3 a surety bond of at least one hundred thousand dollars (\$100,000),
4 or an equivalent means of security acceptable to the board,
5 including insurance, an irrevocable letter of credit, or funds
6 deposited in a trust account or financial institution, to secure
7 payment of any administrative penalties that may be imposed by
8 the board and any fees and costs that may be incurred by the board
9 and that:

10 (1) are related to a license held by the wholesale drug
11 distributor;

12 (2) are authorized under Indiana law; and

13 (3) the wholesale drug distributor fails to pay less than thirty
14 (30) days after the penalties, fees, or costs become final.

15 However, a separate surety bond or an equivalent means of
16 security is not required for a separate location or a company of the
17 wholesale drug distributor.

18 (c) The board may make a claim against a bond or security
19 posted under subsection (b) within one (1) year after the wholesale
20 drug distributor's license is no longer valid or sixty (60) days after
21 the conclusion of:

22 (1) an administrative or legal proceeding before or on behalf
23 of the board that involves the wholesale drug distributor and
24 results in penalties, fees, or costs described in subsection (b);
25 or

26 (2) an appeal of a proceeding described in subdivision (1);
27 whichever occurs later.

28 (d) The board shall inspect each facility where wholesale
29 distribution operations are conducted before initial licensure and
30 periodically thereafter in accordance with a schedule determined
31 by the board, but at least one (1) time in each three (3) year period.

32 (e) A wholesale drug distributor must publicly display or have
33 readily available all licenses and the most recent inspection report
34 administered by the board.

35 ~~(b)~~ (f) A material change in any information in subsection (a) of this
36 section must be submitted to the board at the time of license renewal
37 or within thirty (30) days from the date of the change, whichever occurs
38 first.

39 SECTION 44. IC 25-26-14-15.5 IS ADDED TO THE INDIANA
40 CODE AS A NEW SECTION TO READ AS FOLLOWS
41 [EFFECTIVE JULY 1, 2005]: Sec. 15.5. (a) A wholesale drug
42 distributor that is an authorized distributor of a manufacturer is

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1 **not considered to be an authorized distributor of the manufacturer**
 2 **under this chapter unless:**

- 3 (1) **the manufacturer files the manufacturer's monthly**
 4 **updated list of authorized distributors with the board;**
 5 (2) **the list is available from the manufacturer upon request or**
 6 **on the Internet; and**
 7 (3) **the manufacturer notifies the board of any change to the**
 8 **list within ten (10) days after the change.**

9 (b) **The board shall make available on the board's Internet web**
 10 **site a manufacturer's list of authorized distributors filed as**
 11 **described in subsection (a).**

12 SECTION 45. IC 25-26-14-16 IS AMENDED TO READ AS
 13 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 16. (a) In reviewing,
 14 **for purposes of licensure or renewal of a license under this chapter,**
 15 the qualifications of persons who engage in wholesale distribution of
 16 legend drugs ~~within~~ in Indiana, the board shall consider the following
 17 factors:

- 18 (1) ~~A conviction of the applicant relating to drug samples;~~
 19 ~~wholesale or retail drug distribution; or distribution of controlled~~
 20 ~~substances: finding by the board that the applicant has:~~

21 (A) **violated a law; or**

22 (B) **been disciplined by a regulatory agency for violating a**
 23 **law;**

24 **related to drug distribution in any state.**

25 (2) ~~A felony criminal conviction of the applicant.~~

26 (3) ~~The applicant's past experience in the manufacture or~~
 27 ~~distribution of legend drugs, including controlled substances.~~

28 (4) ~~The furnishing by the applicant of false or fraudulent material~~
 29 ~~in any application made in connection with drug manufacturing~~
 30 ~~or distribution.~~

31 (5) ~~Suspension or revocation of any license held by the~~
 32 ~~applicant or the applicant's owner or the imposition of~~
 33 ~~sanctions against the applicant or the applicant's owner by the~~
 34 ~~federal or a state or local government of any license held by the~~
 35 ~~applicant for the manufacture or distribution of any drugs,~~
 36 ~~including controlled substances.~~

37 (6) ~~Compliance with licensing requirements under previously~~
 38 ~~granted licenses.~~

39 (7) ~~Compliance with requirements to maintain and make available~~
 40 ~~to the board or to federal, state, or local law enforcement officials~~
 41 ~~those records required under this chapter.~~

42 (8) ~~Any other factors or qualifications the board considers~~

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1 relevant to the public health and safety, including whether the
2 granting of the license would not be in the public interest.

3 **(b) In reviewing an application for licensure or renewal of a**
4 **license under this chapter, the board shall consider the results of**
5 **a national criminal history background check (as defined in**
6 **IC 10-13-3-12) for:**

- 7 (1) the applicant;
- 8 (2) all personnel involved in the operations of the wholesale
9 drug distributor;
- 10 (3) the most senior individual responsible for facility
11 operations, purchasing, and inventory control, and the
12 individual to whom the senior individual reports;
- 13 (4) company officers;
- 14 (5) key management personnel;
- 15 (6) principals; and
- 16 (7) owners with at least a ten percent (10%) interest in the
17 wholesale drug distributor, if the wholesale drug distributor
18 is a nonpublicly held company.

19 **The national criminal history background check must be**
20 **conducted at the applicant's expense and must include all states of**
21 **residence since the applicant became eighteen (18) years of age.**

22 **(c) An applicant shall provide and attest to:**

- 23 (1) an affirmation that the applicant has not been involved in
24 or convicted of any criminal or prohibited acts; or
- 25 (2) a statement providing a complete disclosure of the
26 applicant's past criminal convictions and violations of state
27 and federal laws;

28 **regarding drugs.**

29 SECTION 46. IC 25-26-14-16.5 IS ADDED TO THE INDIANA
30 CODE AS A NEW SECTION TO READ AS FOLLOWS
31 [EFFECTIVE JULY 1, 2005]: **Sec. 16.5. (a) A wholesale drug**
32 **distributor shall designate in writing on a form prescribed by the**
33 **board a designated representative for each of the wholesale drug**
34 **distributor's facilities licensed under this chapter.**

35 **(b) A designated representative shall submit to the board an**
36 **application prescribed by the board and provide to the board the**
37 **following:**

- 38 (1) A set of the designated representative's fingerprints, under
39 procedures specified by the board and according to
40 requirements of the state police department under
41 IC 10-13-3-38.5, with the payment of the amount equal to the
42 costs of a national criminal history background check (as

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- 1 defined in IC 10-13-3-12) of the designated representative to
- 2 be obtained by the state police department.
- 3 (2) The date and place of birth of the designated
- 4 representative.
- 5 (3) A list of the occupations, positions of employment, and
- 6 offices held by the designated representative during the
- 7 immediately preceding seven (7) years, including the principal
- 8 business and address of the organization with which the
- 9 occupation, position, or office was associated.
- 10 (4) A statement concerning whether the designated
- 11 representative, during the immediately preceding seven (7)
- 12 years, has been temporarily or permanently enjoined by a
- 13 court from violating a state or federal law regulating the
- 14 possession, control, or distribution of drugs, including details
- 15 of related events.
- 16 (5) A description of any involvement by the designated
- 17 representative with a business that:
- 18 (A) manufactured, administered, prescribed, distributed,
- 19 or stored drugs; and
- 20 (B) was named as a party in a lawsuit;
- 21 during the immediately preceding seven (7) years, including
- 22 investments other than the ownership of stock in a publicly
- 23 traded company or mutual fund.
- 24 (6) A description of any criminal offense of which the
- 25 designated representative has been convicted, regardless of
- 26 whether adjudication of guilt was withheld or whether the
- 27 designated representative pleaded nolo contendere. If the
- 28 designated representative indicates that a criminal conviction
- 29 is under appeal, the designated representative shall submit to
- 30 the board:
- 31 (A) a copy of the notice of appeal; and
- 32 (B) a copy of the final written order of disposition.
- 33 (7) A photograph of the designated representative taken
- 34 within the immediately preceding thirty (30) days under
- 35 procedures specified by the board.
- 36 (8) A list of the name, address, occupation, and date and place
- 37 of birth of each member of the designated representative's
- 38 immediate family, including the designated representative's
- 39 spouse, children, parents, and siblings, and the spouses of the
- 40 designated representative's children and siblings. Information
- 41 collected under this subdivision is confidential.
- 42 (9) Any other information required by the board.

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1 (c) A designated representative must have at least two (2) years
2 of verifiable full-time managerial or supervisory experience in a
3 pharmacy or with a wholesale drug distributor licensed under this
4 chapter or in another state. The designated representative's
5 responsibilities must have included record keeping, storage, and
6 shipment of legend drugs.

7 (d) A designated representative shall not serve as the designated
8 representative for more than one (1) wholesale drug distributor
9 facility at any one (1) time.

10 (e) A designated representative shall be actively involved and
11 aware of the actual daily operations of the wholesale drug
12 distributor as follows:

13 (1) Be employed full time in a managerial position by the
14 wholesale drug distributor.

15 (2) Be physically present at the wholesale drug distributor's
16 facility during normal business hours, except when absent due
17 to illness, family illness or death, scheduled vacation, or
18 another authorized absence.

19 (3) Be aware of and knowledgeable about all policies and
20 procedures pertaining to the operations of the wholesale drug
21 distributor.

22 (f) A designated representative must complete continuing
23 education programs specified by the board regarding state and
24 federal law relevant to the distribution, handling, and storage of
25 legend drugs.

26 SECTION 47. IC 25-26-14-16.6 IS ADDED TO THE INDIANA
27 CODE AS A NEW SECTION TO READ AS FOLLOWS
28 [EFFECTIVE JULY 1, 2005]: Sec. 16.6. (a) A wholesale drug
29 distributor that:

- 30 (1) is licensed under this chapter;
- 31 (2) is located outside Indiana; and
- 32 (3) distributes legend drugs in Indiana;

33 shall designate an agent in Indiana for service of process.

34 (b) A wholesale drug distributor that does not designate an
35 agent under subsection (a) is considered to have designated the
36 secretary of state to be the wholesale drug distributor's true and
37 lawful attorney, upon whom legal process may be served in an
38 action or a proceeding against the wholesale drug distributor
39 arising from the wholesale drug distributor's wholesale
40 distribution operations.

41 (c) The board shall mail a copy of any service of process to a
42 wholesale drug distributor by certified mail, return receipt

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1 requested, postage prepaid, at the address designated by the
2 wholesale drug distributor on the application for licensure
3 submitted under this chapter.

4 (d) Service of process on the secretary of state is sufficient in an
5 action or a proceeding against a wholesale drug distributor that is
6 not licensed under this chapter.

7 SECTION 48. IC 25-26-14-17 IS AMENDED TO READ AS
8 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 17. As a condition for
9 receiving and retaining any a wholesale drug distributor license issued
10 under to this chapter, each an applicant must satisfy the board that the
11 applicant has and will continuously maintain the following:

12 (1) Acceptable storage and handling conditions and facilities
13 standards for each facility at which legend drugs are received,
14 stored, warehoused, handled, held, offered, marketed, or
15 displayed, or from which legend drugs are transported,
16 including:

17 (A) suitable construction of the facility and appropriate
18 monitoring equipment to ensure that legend drugs in the
19 facility are maintained in accordance with labeling or in
20 compliance with official compendium standards;

21 (B) suitable size and construction to facilitate cleaning,
22 maintenance, and proper wholesale distribution
23 operations;

24 (C) adequate storage areas to provide appropriate lighting,
25 ventilation, temperature, sanitation, humidity, space,
26 equipment, and security conditions;

27 (D) a quarantine area for separate storage of legend drugs
28 that are outdated, damaged, deteriorated, misbranded,
29 adulterated, counterfeit, suspected counterfeit, otherwise
30 unfit for distribution, or contained in immediate or sealed
31 secondary containers that have been opened;

32 (E) maintenance of the facility in a clean and orderly
33 condition;

34 (F) maintenance of the facility in a commercial,
35 nonresidential building; and

36 (G) freedom of the facility from infestation.

37 (2) Security of each facility from unauthorized entry as
38 follows:

39 (A) Entry into areas where legend drugs are held is limited
40 to authorized personnel.

41 (B) Each facility is equipped with a security system that
42 includes:

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- ~~(A)~~ (i) an after hours central alarm or a comparable entry detection capability;
- ~~(B)~~ (ii) restricted premises access;
- ~~(C)~~ (iii) adequate outside perimeter lighting; and
- ~~(D)~~ (iv) safeguards against **theft and diversion, including employee theft and theft or diversion facilitated or hidden by tampering with computers or electronic records; and**
- (v) a means of protecting the integrity and confidentiality of data and documents and of making the data and documents readily available to the board and other state and federal law enforcement officials.**

(3) A reasonable system of record keeping ~~that~~ **as follows:**

(A) **The system** describes all the wholesale distributor's activities governed by this chapter for the ~~two (2)~~ **three (3)** year period after the disposition of each product and **all records are maintained for at least three (3) years after disposition of the legend drug to which the record applies.**

(B) **The system** is reasonably accessible as determined by board rules in any inspection authorized by the board.

(C) **The system provides a means to establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of all legend drugs, including the following:**

(i) **For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is an authorized distributor, a pedigree for each distributed legend drug that is on the specified list of susceptible products or that leaves the normal distribution chain of custody from the manufacturer to a wholesale drug distributor, to a pharmacy, and to the patient or the patient's agent.**

(ii) **For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is not an authorized distributor, a pedigree for each distributed legend drug.**

(iii) **After January 1, 2007, at the board's discretion, for each legend drug received and distributed by the wholesale drug distributor, an electronic pedigree developed in accordance with standards and requirements of the board to authenticate, track, and trace legend drugs. The standards and requirements of the board may indicate the information required to be part of the electronic pedigree.**

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(iv) Dates of receipt and distribution or other disposition of the legend drugs by the wholesale drug distributor.

(v) Availability for inspection and photocopying by any authorized official of a local, state, or federal governmental agency for three (3) years after the creation date of the inventories and records.

(D) Onsite electronic inventories and records are immediately available for inspection. Records kept at a central location apart from the inspection site and not electronically retrievable are available for inspection within two (2) working days after a request by an authorized official of a local, state, or federal governmental agency.

(E) The system maintains an ongoing list of persons with whom the wholesale drug distributor does business.

(F) The system provides for reporting counterfeit or suspected counterfeit legend drugs or counterfeiting or suspected counterfeiting activities to the board and federal Food and Drug Administration.

(G) The system provides for mandatory reporting of significant shortages or losses of legend drugs to the board and federal Food and Drug Administration if diversion is known or suspected.

(4) Written policies and procedures to which the wholesale drug distributor adheres for the receipt, security, storage, inventory, transport, shipping, and distribution of legend drugs, and that assure reasonable wholesale distributor preparation for, protection against, and handling of any facility security or operation problems, including the following:

(A) ~~those~~ Facility security or operation problems caused by natural disaster or government emergency.

(B) Correction of inventory inaccuracies. ~~or~~

(C) Product shipping and receiving problems.

~~(D)~~ (D) Quarantine and return to the manufacturer or destruction in accordance with state and federal law of all outdated ~~product~~ products and outdated or expired legend drugs, including appropriate documentation and witnessing.

~~(E)~~ (E) Appropriate disposition of returned goods. ~~and~~

~~(F)~~ (F) Product recalls.

(G) Identifying, recording, and reporting losses or thefts.

(H) Implementation and maintenance of a continuous

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quality improvement system.

(I) Recalls and withdrawals of legend drugs due to:

- (i) an action initiated by the federal Food and Drug Administration or another federal, state, or local governmental agency;**
- (ii) a volunteer action by the manufacturer to remove defective or potentially defective legend drugs from the market; or**
- (iii) an action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design.**

(J) Disposition and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging are not used in counterfeiting activities, including necessary documentation and witnessing in accordance with state and federal law.

(K) Investigation of discrepancies in the inventory involving counterfeit, suspected counterfeit, contraband, or suspected contraband legend drugs and reporting of discrepancies within three (3) business days to the board and any other appropriate state or federal governmental agency.

(L) Reporting of criminal or suspected criminal activities involving the inventory of legend drugs to the board within three (3) business days.

(M) Conducting for cause authentication and random authentication as required under sections 17.2, 17.3, and 17.8 of this chapter.

(5) Written policies and procedures and sufficient inspection procedures for all incoming and outgoing product shipments, including the following:

(A) Upon receipt, visual examination of each shipping container in a manner adequate to identify the legend drugs in the container and to determine whether the legend drugs may be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution.

(B) Upon receipt, review of records by the wholesale drug distributor for the acquisition of legend drugs for accuracy and completeness, considering the:

- (i) total facts and circumstances surrounding each transaction involving the legend drugs; and**

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- (ii) wholesale drug distributors involved.
- (C) Quarantine of a legend drug considered to be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution until:
 - (i) examination and a determination that the legend drug is not outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution; or
 - (ii) the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.
- (D) Written policies and procedures to ensure that a legend drug that was:
 - (i) ordered in error or in excess of need by the wholesale drug distributor;
 - (ii) identified within three (3) business days after receipt as ordered in error or in excess of need; and
 - (iii) maintained such that the legend drug's integrity has not been compromised;
 may be returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired if the appropriate documentation is completed and necessary notations are made to a required pedigree.
- (E) Written policies and procedures to ensure that if the wholesale drug distributor determines that a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired within three (3) business days.
- (F) Written policies and procedures to ensure that if the immediate or sealed outer or secondary container or labeling of a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor:
 - (i) quarantines the legend drug until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired; and

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(ii) provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired within three (3) business days.

(G) Written policies and procedures to ensure that a legend drug that has been opened or used, but is not adulterated, misbranded, counterfeit, or suspected counterfeit, is identified as such and quarantined until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.

(H) Written policies and procedures to ensure that:

(i) a legend drug that will be returned to a manufacturer or wholesale drug distributor is kept under proper conditions for storage, handling, transport, and shipment before the return; and

(ii) documentation showing that proper conditions were maintained is provided to the manufacturer or wholesale drug distributor to which the legend drug is returned.

(I) Inspection of each outgoing shipment for identity of the legend drugs and to ensure that the legend drugs have not been damaged in storage or held under improper conditions.

(J) Written policies and procedures to ensure that if conditions under which a legend drug has been returned to the wholesale drug distributor cast doubt on the legend drug's safety, identity, strength, quality, or purity, the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired unless examination, testing, or other investigation proves that the legend drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a legend drug has been returned cast doubt on the legend drug's safety, identity, strength, quality, or purity, the wholesale drug distributor considers the conditions under which the legend drug has been held, stored, or shipped before or during the legend drug's return and the condition of the legend drug and the legend drug's container, carton, or labeling upon receipt of the returned

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- legend drug.
- (K) Written policies and procedures to ensure that contraband, counterfeit, or suspected counterfeit legend drugs, other evidence of criminal activity, and accompanying documentation are retained until a disposition is authorized by the board and the federal Food and Drug Administration.
- (L) Written policies and procedures to ensure that any shipping, immediate, or sealed outer or secondary container or labeling, and accompanying documentation, suspected of or determined to be counterfeit or fraudulent, are retained until a disposition is authorized by the board and federal Food and Drug Administration.
- (6) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.
- (7) Written policies and procedures to provide for the secure and confidential storage of information with restricted access and to protect the integrity and confidentiality of the information.
- (8) A pedigree as required under this chapter, including an electronic pedigree developed in accordance with standards and requirements of the board under subdivision (3)(C)(iii).
- (9) Appropriate inventory management and control systems to:
 - (A) prevent; and
 - (B) allow detection and documentation of; theft, counterfeiting, or diversion of legend drugs.
- (10) If the wholesale drug distributor is involved in the distribution of controlled substances, registration with the federal Drug Enforcement Administration and board and compliance with all laws related to the storage, handling, transport, shipment, and distribution of controlled substances.
- (11) Isolation of controlled substances from noncontrolled substances and storage of the controlled substances in a secure area in accordance with federal Drug Enforcement Administration security requirements and standards.
- (12) Technology and equipment that allow the wholesale drug distributor to authenticate, track, and trace legend drugs. The technology and equipment meets standards set by the board and is used as required by the board to conduct for cause and random tracking, tracing, and authentication of legend drugs.

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(13) Employment, training, and documentation of the training concerning the proper use of the technology and equipment required under subdivision (12).

(14) Packaging operations in accordance with an official compendium allowing the identification of a compromise in the integrity of the legend drugs due to tampering or adverse storage conditions.

SECTION 49. IC 25-26-14-17.2 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 17.2. (a) A wholesale drug distributor that purchases legend drugs from another wholesale drug distributor and has reason to believe that a legend drug purchased from the other wholesale drug distributor is counterfeit, suspected counterfeit, misbranded, or adulterated shall conduct a for cause authentication of each distribution of the legend drug back to the manufacturer.**

(b) A wholesale drug distributor that has engaged in the distribution of a legend drug for which a purchasing wholesale drug distributor conducts a for cause authentication under subsection (a) shall provide, upon request, detailed information regarding the distribution of the legend drug, including the:

- (1) date of purchase of the legend drug;**
- (2) lot number of the legend drug;**
- (3) sales invoice number of the legend drug; and**
- (4) contact information, including name, address, telephone number, and electronic mail address of the wholesale drug distributor that sold the legend drug.**

(c) If a wholesale drug distributor conducts a for cause authentication under subsection (a) and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

(d) If a wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (a), the wholesale drug distributor shall maintain records of the authentication for three (3) years and shall produce the records for the board and the federal Food and Drug Administration upon request.

SECTION 50. IC 25-26-14-17.3 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS

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1 [EFFECTIVE JULY 1, 2005]: **Sec. 17.3. (a) A wholesale drug**
2 **distributor that purchases legend drugs from another wholesale**
3 **drug distributor shall, at least annually, conduct a random**
4 **authentication of a required pedigree on at least ten percent (10%)**
5 **of sales units of wholesale distributions of legend drugs purchased**
6 **from other wholesale drug distributors.**

7 (b) If a wholesale drug distributor purchases from another
8 wholesale drug distributor a legend drug that is on the specified list
9 of susceptible products, the wholesale drug distributor shall, at
10 least quarterly, conduct a random authentication of a required
11 pedigree on at least ninety percent (90%) of sales units of
12 distributions of legend drugs that are on the specified list of
13 susceptible products and that were purchased from other
14 wholesale drug distributors.

15 (c) A wholesale drug distributor from whom another wholesale
16 drug distributor purchases legend drugs shall cooperate with
17 random authentications of pedigrees described in this section and
18 provide requested information in a timely manner.

19 (d) If a wholesale drug distributor conducts a random
20 authentication under this section and is unable to authenticate each
21 distribution of the legend drug, the wholesale drug distributor shall
22 quarantine the legend drug and report the circumstances to the
23 board and the federal Food and Drug Administration not more
24 than ten (10) business days after completing the attempted
25 authentication.

26 SECTION 51. IC 25-26-14-17.8 IS ADDED TO THE INDIANA
27 CODE AS A NEW SECTION TO READ AS FOLLOWS
28 [EFFECTIVE JULY 1, 2005]: **Sec. 17.8. (a) A wholesale drug**
29 **distributor licensed under this chapter that purchases legend drugs**
30 **from a wholesale drug distributor that is not licensed under this**
31 **chapter shall act with due diligence as required under this section.**

32 (b) Before the initial purchase of legend drugs from the
33 unlicensed wholesale drug distributor, the licensed wholesale drug
34 distributor shall obtain the following information from the
35 unlicensed wholesale drug distributor:

- 36 (1) A list of states in which the unlicensed wholesale drug
37 distributor is licensed.
- 38 (2) A list of states into which the unlicensed wholesale drug
39 distributor ships legend drugs.
- 40 (3) Copies of all state and federal regulatory licenses and
41 registrations held by the unlicensed wholesale drug
42 distributor.

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- 1 (4) The unlicensed wholesale drug distributor's most recent
2 facility inspection reports.
- 3 (5) Information regarding general and product liability
4 insurance maintained by the unlicensed wholesale drug
5 distributor, including copies of relevant policies.
- 6 (6) A list of other names under which the unlicensed wholesale
7 drug distributor does business or has been previously known.
- 8 (7) A list of corporate officers and managerial employees of
9 the unlicensed wholesale drug distributor.
- 10 (8) A list of all owners of the unlicensed wholesale drug
11 distributor that own more than ten percent (10%) of the
12 unlicensed wholesale drug distributor, unless the unlicensed
13 wholesale drug distributor is publicly traded.
- 14 (9) A list of all disciplinary actions taken against the
15 unlicensed wholesale drug distributor by state and federal
16 agencies.
- 17 (10) A description, including the address, dimensions, and
18 other relevant information, of each facility used by the
19 unlicensed wholesale drug distributor for legend drug storage
20 and distribution.
- 21 (11) A description of legend drug import and export activities
22 of the unlicensed wholesale drug distributor.
- 23 (12) A description of the unlicensed wholesale drug
24 distributor's procedures to ensure compliance with this
25 chapter.
- 26 (13) A statement:
- 27 (A) as to whether; and
- 28 (B) of the identity of each manufacturer for which;
29 the unlicensed wholesale drug distributor is an authorized
30 distributor.
- 31 (c) Before the initial purchase of legend drugs from an
32 unlicensed wholesale drug distributor, the licensed wholesale drug
33 distributor shall:
- 34 (1) request that the board obtain and consider the results of
35 a national criminal history background check (as defined in
36 IC 10-13-3-12) through the state police department of all
37 individuals associated with the unlicensed wholesale drug
38 distributor as specified for licensure of a wholesale drug
39 distributor under section 16(b) of this chapter; and
- 40 (2) verify the unlicensed wholesale drug distributor's status as
41 an authorized distributor, if applicable.
- 42 (d) If an unlicensed wholesale drug distributor's facility has not

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1 **been inspected by the board or the board's agent within three (3)**
2 **years after a contemplated purchase described in subsection (a),**
3 **the licensed wholesale drug distributor shall conduct an inspection**
4 **of the unlicensed wholesale drug distributor's facility:**

5 **(1) before the initial purchase of legend drugs from the**
6 **unlicensed wholesale drug distributor; and**

7 **(2) at least once every three (3) years unless the unlicensed**
8 **wholesale drug distributor's facility has been inspected by the**
9 **board, or the board's agent, during the same period;**

10 **to ensure compliance with applicable laws and regulations relating**
11 **to the storage and handling of legend drugs. A third party may be**
12 **engaged to conduct the site inspection on behalf of the licensed**
13 **wholesale drug distributor.**

14 **(e) At least annually, a licensed wholesale drug distributor that**
15 **purchases legend drugs from an unlicensed wholesale drug**
16 **distributor shall ensure that the unlicensed wholesale drug**
17 **distributor maintains a record keeping system that meets the**
18 **requirements of section 17(3) of this chapter.**

19 **(f) If a licensed wholesale drug distributor that purchases legend**
20 **drugs from an unlicensed wholesale drug distributor has reason to**
21 **believe that a legend drug purchased from the unlicensed wholesale**
22 **drug distributor is misbranded, adulterated, counterfeit, or**
23 **suspected counterfeit, the licensed wholesale drug distributor shall**
24 **conduct a for cause authentication of each distribution of the**
25 **legend drug back to the manufacturer.**

26 **(g) An unlicensed wholesale drug distributor that has engaged**
27 **in the distribution of a legend drug for which a licensed wholesale**
28 **drug distributor conducts a for cause authentication under**
29 **subsection (f) shall provide, upon request, detailed information**
30 **regarding the distribution of the legend drug, including the:**

31 **(1) date of purchase of the legend drug;**

32 **(2) lot number of the legend drug;**

33 **(3) sales invoice number of the legend drug; and**

34 **(4) contact information, including name, address, telephone**
35 **number, and any electronic mail address of the unlicensed**
36 **wholesale drug distributor that sold the legend drug.**

37 **(h) If a licensed wholesale drug distributor conducts a for cause**
38 **authentication under subsection (f) and is unable to authenticate**
39 **each distribution of the legend drug, the licensed wholesale drug**
40 **distributor shall quarantine the legend drug and report the**
41 **circumstances to the board and the federal Food and Drug**
42 **Administration within ten (10) business days after completing the**

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attempted authentication.

(i) If a licensed wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (f), the licensed wholesale drug distributor shall maintain records of the authentication for three (3) years and shall provide the records to the board upon request.

(j) A licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall, at least annually, conduct random authentications of required pedigrees on at least ten percent (10%) of sales units of distributions of legend drugs that were purchased from unlicensed wholesale drug distributors.

(k) A licensed wholesale drug distributor that has purchased a legend drug that is on the specified list of susceptible products shall, at least quarterly, conduct random authentications of required pedigrees on at least ninety percent (90%) of sales units of distributions of legend drugs that:

- (1) are on the specified list of susceptible products; and
- (2) were purchased from unlicensed wholesale drug distributors.

(l) An unlicensed wholesale drug distributor from which a licensed wholesale drug distributor has purchased legend drugs shall cooperate with the random authentications of pedigrees under this section and provide requested information in a timely manner.

(m) If a wholesale drug distributor conducts a random authentication under subsection (j) or (k) and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

SECTION 52. IC 25-26-14-17.9 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 17.9. A wholesale drug distributor licensed under this chapter may not use a trade name or business name identical to a trade name or business name used by another wholesale drug distributor licensed under this chapter.**

SECTION 53. IC 25-26-14-20 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 20. (a) A person employed in wholesale distribution must have appropriate education or experience to assume responsibility for positions related to compliance**

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with licensing requirements.

(b) Before employing a person to be engaged in the operation and handling of legend drugs, a wholesale drug distributor shall request that the board obtain and consider the results of a national criminal history background check (as defined in IC 10-13-3-12) through the state police department for the person.

SECTION 54. IC 25-26-14-21.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 21.5. (a) A person may not perform, cause the performance of, or aid the performance of the following:**

- (1) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a legend drug that is adulterated, misbranded, counterfeit, suspected counterfeit, or is otherwise unfit for distribution.**
- (2) The adulteration, misbranding, or counterfeiting of a legend drug.**
- (3) The receipt of a legend drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit, and the delivery or proffered delivery of the legend drug for pay or otherwise.**
- (4) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a legend drug or the commission of another act with respect to a legend drug that results in the legend drug being misbranded.**
- (5) Forging, counterfeiting, simulating, or falsely representing a legend drug using a mark, stamp, tag, label, or other identification device without the authorization of the manufacturer.**
- (6) The purchase or receipt of a legend drug from a person that is not licensed to distribute legend drugs to the purchaser or recipient.**
- (7) The sale or transfer of a legend drug to a person that is not authorized under the law of the jurisdiction in which the person receives the legend drug to purchase or receive legend drugs from the person selling or transferring the legend drug.**
- (8) Failure to maintain or provide records as required under this chapter.**
- (9) Providing the board, a representative of the board, or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to this chapter.**

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- 1 **(10) The wholesale distribution of a legend drug that was:**
 2 **(A) purchased by a public or private hospital or other**
 3 **health care entity;**
 4 **(B) donated or supplied at a reduced price to a charitable**
 5 **organization; or**
 6 **(C) stolen or obtained by fraud or deceit.**
 7 **(11) Obtaining or attempting to obtain a legend drug by**
 8 **fraud, deceit, misrepresentation, or engaging in fraud, deceit,**
 9 **or misrepresentation in the distribution of a legend drug.**
 10 **(12) Failure to obtain, authenticate, or provide a required**
 11 **pedigree.**
 12 **(13) The receipt of a legend drug through wholesale**
 13 **distribution without first receiving a required pedigree**
 14 **attested to as accurate and complete by the wholesale drug**
 15 **distributor.**
 16 **(14) Distributing a legend drug that was previously dispensed**
 17 **by a retail pharmacy or distributed by a practitioner.**
 18 **(15) Failure to report an act prohibited by this section.**

19 **(b) The board may impose the following sanctions if, after a**
 20 **hearing under IC 4-21.5-3, the board finds that a person has**
 21 **violated subsection (a):**

- 22 **(1) Revoke the wholesale drug distributor's license issued**
 23 **under this chapter if the person is a wholesale drug**
 24 **distributor.**
 25 **(2) Assess a civil penalty against the person. A civil penalty**
 26 **assessed under this subdivision may not be more than ten**
 27 **thousand dollars (\$10,000) per violation.**

28 SECTION 55. IC 25-26-14-26 IS AMENDED TO READ AS
 29 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 26. **(a) A person that**
 30 **who knowingly or intentionally engages in the wholesale distribution**
 31 **of a legend drug without a license issued under this chapter commits**
 32 **a Class D felony.**

33 **(b) A person who engages in the wholesale distribution of a**
 34 **legend drug and:**

- 35 **(1) who, with intent to defraud or deceive:**
 36 **(A) fails to obtain or deliver to another person a complete**
 37 **and accurate required pedigree concerning a legend drug**
 38 **before:**
 39 **(i) obtaining the legend drug from another person; or**
 40 **(ii) transferring the legend drug to another person; or**
 41 **(B) falsely swears or certifies that the person has**
 42 **authenticated any documents related to the wholesale**

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- 1 **distribution of legend drugs;**
 2 **(2) who knowingly or intentionally:**
 3 **(A) destroys, alters, conceals, or fails to maintain a**
 4 **complete and accurate required pedigree concerning a**
 5 **legend drug in the person's possession;**
 6 **(B) purchases or receives legend drugs from a person not**
 7 **authorized to distribute legend drugs in wholesale**
 8 **distribution;**
 9 **(C) sells, barter, brokers, or transfers a legend drug to a**
 10 **person not authorized to purchase the legend drug in the**
 11 **jurisdiction in which the person receives the legend drug**
 12 **in a wholesale distribution;**
 13 **(D) forges, counterfeits, or falsely creates a pedigree;**
 14 **(E) falsely represents a factual matter contained in a**
 15 **pedigree; or**
 16 **(F) fails to record material information required to be**
 17 **recorded in a pedigree; or**
 18 **(3) who:**
 19 **(A) possesses a required pedigree concerning a legend**
 20 **drug;**
 21 **(B) knowingly or intentionally fails to authenticate the**
 22 **matters contained in the pedigree as required; and**
 23 **(C) distributes or attempts to further distribute the legend**
 24 **drug;**
 25 **commits a Class D felony.**
 26 SECTION 56. IC 25-26-14-27 IS AMENDED TO READ AS
 27 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 27. A wholesale drug
 28 distributor that fails to comply with the conditions **and requirements**
 29 described in section 17, **17.2, 17.3, 17.8, 17.9, or 20** of this chapter
 30 commits a Class D felony.
 31 SECTION 57. IC 25-26-15-10 IS AMENDED TO READ AS
 32 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 10. As used in this
 33 chapter, "prescription" means a written order or an order transmitted by
 34 other means of communication that is immediately reduced to writing
 35 by the pharmacist **or, for electronically transmitted orders, recorded**
 36 **in an electronic format** from an optometrist to or for an ultimate user
 37 for a drug or device, containing:
 38 (1) the name and address of the patient;
 39 (2) the date of issue;
 40 (3) the name and strength or size (if applicable) of the drug or
 41 device;
 42 (4) the amount to be dispensed (unless indicated by directions and

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- 1 duration of therapy);
- 2 (5) adequate directions for the proper use of the drug or device by
- 3 the patient;
- 4 (6) the name and certification number of the prescribing
- 5 optometrist; and
- 6 (7) ~~the signature of the optometrist~~ if the prescription:
- 7 (A) is in written form, **the signature of the optometrist; or**
- 8 **(B) is in electronic form, the electronic signature of the**
- 9 **optometrist.**

10 SECTION 58. IC 25-26-20-4 IS AMENDED TO READ AS
 11 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 4. (a) Except as
 12 provided in subsections (b) and (c), unadulterated drugs that meet the
 13 requirements set forth in ~~IC 25-26-13-25(i)~~ **IC 25-26-13-25(j)** may be
 14 donated without a prescription or drug order to the regional drug
 15 repository program by the following:

- 16 (1) A pharmacist or pharmacy.
 - 17 (2) A wholesale drug distributor.
 - 18 (3) A hospital licensed under IC 16-21.
 - 19 (4) A health care facility (as defined in IC 16-18-2-161).
 - 20 (5) A hospice.
 - 21 (6) A practitioner.
 - 22 (b) An unadulterated drug that:
 - 23 (1) was returned under IC 25-26-13-25; and
 - 24 (2) was prescribed for a Medicaid recipient;
- 25 may not be donated under this section unless the Medicaid program has
 26 been credited for the product cost of the drug as provided in policies
 27 under the Medicaid program.

28 (c) A controlled drug may not be donated under this section.

29 SECTION 59. IC 27-13-38-2 IS AMENDED TO READ AS
 30 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 2. Subject to
 31 IC 16-42-22:

- 32 (1) a pharmacist shall not substitute; and
 - 33 (2) a health maintenance organization shall not require the
 - 34 substitution of;
- 35 a different single source brand name drug for a single source brand
 36 name drug written on a prescription form **or electronically**
 37 **transmitted to a pharmacy** unless the substitution is approved by the
 38 prescribing provider.

39 SECTION 60. IC 34-24-1-1 IS AMENDED TO READ AS
 40 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 1. (a) The following
 41 may be seized:

- 42 (1) All vehicles (as defined by IC 35-41-1), if they are used or are

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1 intended for use by the person or persons in possession of them to
 2 transport or in any manner to facilitate the transportation of the
 3 following:
 4 (A) A controlled substance for the purpose of committing,
 5 attempting to commit, or conspiring to commit any of the
 6 following:
 7 (i) Dealing in or manufacturing cocaine, a narcotic drug, or
 8 methamphetamine (IC 35-48-4-1).
 9 (ii) Dealing in a schedule I, II, or III controlled substance
 10 (IC 35-48-4-2).
 11 (iii) Dealing in a schedule IV controlled substance
 12 (IC 35-48-4-3).
 13 (iv) Dealing in a schedule V controlled substance
 14 (IC 35-48-4-4).
 15 (v) Dealing in a counterfeit substance (IC 35-48-4-5).
 16 (vi) Possession of cocaine, a narcotic drug, or
 17 methamphetamine (IC 35-48-4-6).
 18 (vii) Dealing in paraphernalia (IC 35-48-4-8.5).
 19 (viii) Dealing in marijuana, hash oil, or hashish
 20 (IC 35-48-4-10).
 21 (B) Any stolen (IC 35-43-4-2) or converted property
 22 (IC 35-43-4-3) if the retail or repurchase value of that property
 23 is one hundred dollars (\$100) or more.
 24 (C) Any hazardous waste in violation of IC 13-30-6-6.
 25 (D) A bomb (as defined in IC 35-41-1-4.3) or weapon of mass
 26 destruction (as defined in IC 35-41-1-29.4) used to commit,
 27 used in an attempt to commit, or used in a conspiracy to
 28 commit an offense under IC 35-47 as part of or in furtherance
 29 of an act of terrorism (as defined by IC 35-41-1-26.5).
 30 (2) All money, negotiable instruments, securities, weapons,
 31 communications devices, or any property used to commit, used in
 32 an attempt to commit, or used in a conspiracy to commit an
 33 offense under IC 35-47 as part of or in furtherance of an act of
 34 terrorism or commonly used as consideration for a violation of
 35 IC 35-48-4 (other than items subject to forfeiture under
 36 IC 16-42-20-5 or IC 16-6-8.5-5.1 before its repeal):
 37 (A) furnished or intended to be furnished by any person in
 38 exchange for an act that is in violation of a criminal statute;
 39 (B) used to facilitate any violation of a criminal statute; or
 40 (C) traceable as proceeds of the violation of a criminal statute.
 41 (3) Any portion of real or personal property purchased with
 42 money that is traceable as a proceed of a violation of a criminal

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1 statute.

2 (4) A vehicle that is used by a person to:

3 (A) commit, attempt to commit, or conspire to commit;

4 (B) facilitate the commission of; or

5 (C) escape from the commission of;

6 murder (IC 35-42-1-1), kidnapping (IC 35-42-3-2), criminal

7 confinement (IC 35-42-3-3), rape (IC 35-42-4-1), child molesting

8 (IC 35-42-4-3), or child exploitation (IC 35-42-4-4), or an offense

9 under IC 35-47 as part of or in furtherance of an act of terrorism.

10 (5) Real property owned by a person who uses it to commit any of

11 the following as a Class A felony, a Class B felony, or a Class C

12 felony:

13 (A) Dealing in or manufacturing cocaine, a narcotic drug, or

14 methamphetamine (IC 35-48-4-1).

15 (B) Dealing in a schedule I, II, or III controlled substance

16 (IC 35-48-4-2).

17 (C) Dealing in a schedule IV controlled substance

18 (IC 35-48-4-3).

19 (D) Dealing in marijuana, hash oil, or hashish (IC 35-48-4-10).

20 (6) Equipment and recordings used by a person to commit fraud

21 under IC 35-43-5-4(11).

22 (7) Recordings sold, rented, transported, or possessed by a person

23 in violation of IC 24-4-10.

24 (8) Property (as defined by IC 35-41-1-23) or an enterprise (as

25 defined by IC 35-45-6-1) that is the object of a corrupt business

26 influence violation (IC 35-45-6-2).

27 (9) Unlawful telecommunications devices (as defined in

28 IC 35-45-13-6) and plans, instructions, or publications used to

29 commit an offense under IC 35-45-13.

30 (10) Any equipment used or intended for use in preparing,

31 photographing, recording, videotaping, digitizing, printing,

32 copying, or disseminating matter in violation of IC 35-42-4-4.

33 (11) Destructive devices used, possessed, transported, or sold in

34 violation of IC 35-47.5.

35 (12) Cigarettes that are sold in violation of IC 24-3-5.2, cigarettes

36 that a person attempts to sell in violation of IC 24-3-5.2, and other

37 personal property owned and used by a person to facilitate a

38 violation of IC 24-3-5.2.

39 (13) Tobacco products that are sold in violation of IC 24-3-5,

40 tobacco products that a person attempts to sell in violation of

41 IC 24-3-5, and other personal property owned and used by a

42 person to facilitate a violation of IC 24-3-5.

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1 (14) If a person is convicted of an offense specified in
2 IC 25-26-14-26(b) or IC 35-43-10, the following real or
3 personal property:

4 (A) Property used or intended to be used to commit,
5 facilitate, or promote the commission of the offense.

6 (B) Property constituting, derived from, or traceable to the
7 gross proceeds that the person obtained directly or
8 indirectly as a result of the offense.

9 (b) A vehicle used by any person as a common or contract carrier in
10 the transaction of business as a common or contract carrier is not
11 subject to seizure under this section, unless it can be proven by a
12 preponderance of the evidence that the owner of the vehicle knowingly
13 permitted the vehicle to be used to engage in conduct that subjects it to
14 seizure under subsection (a).

15 (c) Equipment under subsection (a)(10) may not be seized unless it
16 can be proven by a preponderance of the evidence that the owner of the
17 equipment knowingly permitted the equipment to be used to engage in
18 conduct that subjects it to seizure under subsection (a)(10).

19 (d) Money, negotiable instruments, securities, weapons,
20 communications devices, or any property commonly used as
21 consideration for a violation of IC 35-48-4 found near or on a person
22 who is committing, attempting to commit, or conspiring to commit any
23 of the following offenses shall be admitted into evidence in an action
24 under this chapter as prima facie evidence that the money, negotiable
25 instrument, security, or other thing of value is property that has been
26 used or was to have been used to facilitate the violation of a criminal
27 statute or is the proceeds of the violation of a criminal statute:

28 (1) IC 35-48-4-1 (dealing in or manufacturing cocaine, a narcotic
29 drug, or methamphetamine).

30 (2) IC 35-48-4-2 (dealing in a schedule I, II, or III controlled
31 substance).

32 (3) IC 35-48-4-3 (dealing in a schedule IV controlled substance).

33 (4) IC 35-48-4-4 (dealing in a schedule V controlled substance)
34 as a Class B felony.

35 (5) IC 35-48-4-6 (possession of cocaine, a narcotic drug, or
36 methamphetamine) as a Class A felony, Class B felony, or Class
37 C felony.

38 (6) IC 35-48-4-10 (dealing in marijuana, hash oil, or hashish) as
39 a Class C felony.

40 SECTION 61. IC 35-43-10 IS ADDED TO THE INDIANA CODE
41 AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE
42 JULY 1, 2005]:

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Chapter 10. Legend Drug Deception

Sec. 1. The definitions in IC 25-26-14 apply throughout this chapter.

Sec. 2. A person who knowingly or intentionally:

- (1) possesses a contraband legend drug;**
- (2) sells, delivers, or possesses with intent to sell or deliver a contraband legend drug;**
- (3) forges, counterfeits, or falsely creates a label for a legend drug or falsely represents a factual matter contained on a label of a legend drug; or**
- (4) manufactures, purchases, sells, delivers, brings into Indiana, or possesses a contraband legend drug;**

commits legend drug deception, a Class D felony.

Sec. 3. A person:

- (1) who knowingly or intentionally manufactures, purchases, sells, delivers, brings into Indiana, or possesses a contraband legend drug; and**
- (2) whose act under subdivision (1) results in the death of an individual;**

commits legend drug deception resulting in death, a Class A felony.

SECTION 62. IC 35-48-3-9 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 9. (a) Except for dosages medically required for a period of not more than forty-eight (48) hours that are dispensed by or on the direction of a practitioner or medication dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in schedule II may be dispensed without the written prescription of a practitioner.

(b) In emergency situations, as defined by rule of the board, schedule II drugs may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of section 7 of this chapter. No prescription for a schedule II substance may be refilled.

(c) Except for dosages medically required for a period of not more than forty-eight (48) hours that are dispensed by or on the direction of a practitioner, or medication dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in schedule III or IV, which is a prescription drug as determined under IC 16-42-19, shall not be dispensed without a written or oral prescription of a practitioner. The prescription shall not be filled or refilled more than six (6) months after the date thereof or be refilled more than five (5) times, unless renewed by the practitioner.

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1 **Prescriptions for schedule III, IV, and V controlled substances may**
2 **be transmitted by facsimile from the practitioner or the agent of**
3 **the practitioner to a pharmacy. The facsimile prescription is**
4 **equivalent to an original prescription to the extent permitted under**
5 **federal law.**

6 (d) A controlled substance included in schedule V shall not be
7 distributed or dispensed other than for a medical purpose.

8 SECTION 63. IC 35-48-7-5 IS AMENDED TO READ AS
9 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 5. As used in this
10 chapter, "identification number" refers to **the following:**

- 11 (1) The unique number contained on any of the following:
 - 12 ~~(1)~~ (A) A valid driver's license of a recipient or a recipient's
 - 13 representative issued under Indiana law or the law of any other
 - 14 state.
 - 15 ~~(2)~~ (B) A recipient's or a recipient representative's valid
 - 16 military identification card.
 - 17 ~~(3)~~ (C) A valid identification card of a recipient or a recipient's
 - 18 representative issued by:
 - 19 ~~(A)~~ (i) the bureau of motor vehicles and described in
 - 20 IC 9-24-16-3; or
 - 21 ~~(B)~~ (ii) any other state and that is similar to the identification
 - 22 card issued by the bureau of motor vehicles.
 - 23 ~~(4)~~ (D) If the recipient is an animal:
 - 24 ~~(A)~~ (i) the valid driver's license issued under Indiana law or
 - 25 the law of any other state;
 - 26 ~~(B)~~ (ii) the valid military identification card; or
 - 27 ~~(C)~~ (iii) the valid identification card issued by the bureau of
 - 28 motor vehicles and described in IC 9-24-16-3 or a valid
 - 29 identification card of similar description that is issued by
 - 30 any other state;
 - 31 of the animal's owner.

32 (2) **The identification number or phrase designated by the**
33 **central repository.**

34 SECTION 64. IC 35-48-7-8 IS AMENDED TO READ AS
35 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 8. The advisory
36 committee shall provide for a controlled substance prescription
37 monitoring program that includes the following components:

- 38 (1) Each time a controlled substance designated by the advisory
- 39 committee under IC 35-48-2-5 through IC 35-48-2-10 is
- 40 dispensed, the dispenser shall transmit to the central repository
- 41 the following information:
 - 42 (A) The recipient's name.

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- 1 (B) The recipient's or the recipient representative's
- 2 identification number **or the identification number or**
- 3 **phrase designated by the central repository.**
- 4 (C) The recipient's date of birth.
- 5 (D) The national drug code number of the controlled substance
- 6 dispensed.
- 7 (E) The date the controlled substance is dispensed.
- 8 (F) The quantity of the controlled substance dispensed.
- 9 (G) The number of days of supply dispensed.
- 10 (H) The dispenser's United States Drug Enforcement Agency
- 11 registration number.
- 12 (I) The prescriber's United States Drug Enforcement Agency
- 13 registration number.
- 14 (J) An indication as to whether the prescription was
- 15 transmitted to the pharmacist orally or in writing.
- 16 (2) The information required to be transmitted under this section
- 17 must be transmitted not more than fifteen (15) days after the date
- 18 on which a controlled substance is dispensed.
- 19 (3) A dispenser shall transmit the information required under this
- 20 section by:
- 21 (A) an electronic device compatible with the receiving device
- 22 of the central repository;
- 23 (B) a computer diskette;
- 24 (C) a magnetic tape; or
- 25 (D) a pharmacy universal claim form;
- 26 that meets specifications prescribed by the advisory committee.
- 27 (4) The advisory committee may require that prescriptions for
- 28 controlled substances be written on a one (1) part form that
- 29 cannot be duplicated. However, the advisory committee may not
- 30 apply such a requirement to prescriptions filled at a pharmacy
- 31 with a Type II permit (as described in IC 25-26-13-17) and
- 32 operated by a hospital licensed under IC 16-21, or prescriptions
- 33 ordered for and dispensed to bona fide enrolled patients in
- 34 facilities licensed under IC 16-28. The committee may not require
- 35 multiple copy prescription forms and serially numbered
- 36 prescription forms for any prescriptions written. The committee
- 37 may not require different prescription forms for any individual
- 38 drug or group of drugs. Prescription forms required under this
- 39 subdivision must be jointly approved by the committee and by the
- 40 Indiana board of pharmacy established by IC 25-26-13-3.
- 41 (5) The costs of the program.

SECTION 65. [EFFECTIVE JULY 1, 2005] (a) **IC 25-26-14, as**

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amended by this act, applies:

(1) after June 30, 2005, for an initial license issued under IC 25-26-14, as amended by this act; and

(2) on the first expiration date occurring after December 31, 2005, for renewal of a license issued under IC 25-26-14, before amendment by this act.

(b) The Indiana board of pharmacy established by IC 25-26-13-3 may establish an electronic pedigree pilot program to authenticate, track, and trace legend drugs. The pilot program must include participation of drug manufacturers, wholesale drug distributors, and pharmacies that are licensed in Indiana. The board may establish the requirements and guidelines for the pilot program.

(c) Before June 30, 2007, the Indiana board of pharmacy established by IC 25-26-13-3 shall conduct a study of the electronic pedigree pilot program. The study must include consultation with manufacturers, distributors, and pharmacies that participate in the electronic pedigree pilot program. The study may include the consultation with manufacturers, distributors, and pharmacies that do not participate in the electronic pedigree pilot program. Based on the results of the study, the board shall determine a date to implement a mandatory electronic pedigree program. However, the board may not implement a mandatory electronic pedigree program until after the board has completed the study under this subsection.

(d) This SECTION expires December 31, 2007.

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COMMITTEE REPORT

Madam President: The Senate Committee on Economic Development and Technology, to which was referred Senate Bill No. 590, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill DO PASS.

(Reference is made to Senate Bill 590 as introduced.)

FORD, Chairperson

Committee Vote: Yeas 9, Nays 0.

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SENATE MOTION

Madam President: I move that Senator Simpson be as coauthor of Senate Bill 590.

RIEGSECKER

 SENATE MOTION

Madam President: I move that Senate Bill 590 be amended to read as follows:

Page 1, between lines 10 and 11, begin a new paragraph and insert:
 "SECTION 2. IC 16-18-2-106.4 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION TO READ AS FOLLOWS** [EFFECTIVE JULY 1, 2005]: **Sec. 106.4. For purposes of IC 16-42-3, IC 16-42-19, and IC 16-42-22, "electronically transmitted" or "electronic transmission" means the transmission of a prescription in electronic form. The term does not include transmission of a prescription by facsimile.**"

Page 2, line 22, strike "pharmacist;" and insert "**pharmacist or pharmacist intern (as defined in IC 25-26-13-2);**";

Page 5, line 27, strike "pharmacist;" and insert "**pharmacist or pharmacist intern (as defined in IC 25-26-13-2);**";

Page 6, line 10, delete "practitioner:" and insert "**practitioner must:**".

Page 6, line 11, delete "must".

Page 6, line 12, delete "may".

Page 6, line 12, delete "or".

Page 7, line 10, delete "indicate" and insert "**indicating with the electronic prescription**".

Page 7, line 11, delete "permitted electronically." and insert "**permitted.**".

Page 7, line 12, delete "or electronically transmits".

Page 7, line 13, delete "instructions".

Page 9, line 26, delete "the:" and insert "**a**".

Page 9, line 27, delete "(1)".

Page 9, line 27, delete "information".

Page 9, line 27, delete "form; or" and insert "**form. The term does not include the transmission of a prescription by facsimile.**".

Page 9, run in lines 26 through 27.

Page 9, delete lines 28 through 29.

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Page 12, between lines 1 and 2, begin a new paragraph and insert:
 "SECTION 14. IC 25-26-13-4 IS AMENDED TO READ AS
 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 4. (a) The board may:

(1) promulgate rules and regulations under IC 4-22-2 for implementing and enforcing this chapter;

(2) establish requirements and tests to determine the moral, physical, intellectual, educational, scientific, technical, and professional qualifications for applicants for pharmacists' licenses;

(3) refuse to issue, deny, suspend, or revoke a license or permit or place on probation or fine any licensee or permittee under this chapter;

(4) regulate the sale of drugs and devices in the state of Indiana;

(5) impound, embargo, confiscate, or otherwise prevent from disposition any drugs, medicines, chemicals, poisons, or devices which by inspection are deemed unfit for use or would be dangerous to the health and welfare of the citizens of the state of Indiana; the board shall follow those embargo procedures found in IC 16-42-1-18 through IC 16-42-1-31, and persons may not refuse to permit or otherwise prevent members of the board or their representatives from entering such places and making such inspections;

(6) prescribe minimum standards with respect to physical characteristics of pharmacies, as may be necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public;

(7) subject to IC 25-1-7, investigate complaints, subpoena witnesses, schedule and conduct hearings on behalf of the public interest on any matter under the jurisdiction of the board;

(8) prescribe the time, place, method, manner, scope, and subjects of licensing examinations which shall be given at least twice annually; and

(9) perform such other duties and functions and exercise such other powers as may be necessary to implement and enforce this chapter.

(b) The board shall adopt rules under IC 4-22-2 for the following:

(1) Establishing standards for the competent practice of pharmacy.

(2) Establishing the standards for a pharmacist to counsel individuals regarding the proper use of drugs.

(c) The board may grant or deny a temporary variance to a rule it has adopted if:

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- (1) the board has adopted rules which set forth the procedures and standards governing the grant or denial of a temporary variance; and
- (2) the board sets forth in writing the reasons for a grant or denial of a temporary variance.

(d) The board shall adopt rules and procedures, in consultation with the medical licensing board, concerning the electronic transmission of prescriptions. The rules adopted under this subsection must address the following:

- (1) Privacy protection for the practitioner and the practitioner's patient.**
- (2) Security of the electronic transmission.**
- (3) A process for approving electronic data intermediaries for the electronic transmission of prescriptions.**
- (4) Use of a practitioner's United States Drug Enforcement Agency registration number.**
- (5) Protection of the practitioner from identity theft or fraudulent use of the practitioner's prescribing authority."**

Page 12, line 13, delete "facsimile,".

Page 12, line 15, delete "intermediary:" and insert "**intermediary that is approved by the board:**".

Page 15, between lines 14 and 15, begin a new paragraph and insert:

"SECTION 16. IC 25-26-13-25.5 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 25.5. A prescription may be transmitted electronically from a practitioner to a pharmacist only through the use of an electronic data intermediary approved by the board.**".

Re-number all SECTIONS consecutively.

(Reference is to SB 590 as printed February 1, 2005.)

RIEGSECKER

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COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred Senate Bill 590, 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 10-13-3-38.5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 38.5. (a) Under federal P.L.92-544 (86 Stat. 1115), the department may use an individual's fingerprints submitted by the individual for the following purposes:

(1) Determining the individual's suitability for employment with the state, or as an employee of a contractor of the state, in a position:

(A) that has a job description that includes contact with, care of, or supervision over a person less than eighteen (18) years of age;

(B) that has a job description that includes contact with, care of, or supervision over an endangered adult (as defined in IC 12-10-3-2), except the individual is not required to meet the standard for harmed or threatened with harm set forth in IC 12-10-3-2(a)(3);

(C) at a state institution managed by the office of the secretary of family and social services or state department of health;

(D) at the Indiana School for the Deaf established by IC 20-16-2-1;

(E) at the Indiana School for the Blind established by IC 20-15-2-1;

(F) at a juvenile detention facility;

(G) with the gaming commission under IC 4-33-3-16;

(H) with the department of financial institutions under IC 28-11-2-3; or

(I) that has a job description that includes access to or supervision over state financial or personnel data, including state warrants, banking codes, or payroll information pertaining to state employees.

(2) Identification in a request related to an application for a teacher's license submitted to the professional standards board established under IC 20-1-1.4.

(3) Use by the Indiana board of pharmacy in determining the individual's suitability for a position or employment with a wholesale drug distributor, as specified in IC 25-26-14-16(b),

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IC 25-26-14-16.5(b), IC 25-26-14-17.8(c), and IC 25-26-14-20.

An applicant shall submit the fingerprints in an appropriate format or on forms provided for the employment or license application. The department shall charge each applicant the fee established under section 28 of this chapter and by federal authorities to defray the costs associated with a search for and classification of the applicant's fingerprints. The department may forward fingerprints submitted by an applicant to the Federal Bureau of Investigation or any other agency for processing. The state personnel department or the agency to which the applicant is applying for employment or a license may receive the results of all fingerprint investigations.

(b) An applicant who is an employee of the state may not be charged under subsection (a).

(c) Subsection (a)(1) does not apply to an employee of a contractor of the state if the contract involves the construction or repair of a capital project or other public works project of the state."

Page 2, line 35, after "writing" insert "**or is entered into an electronic format**".

Page 2, line 35, delete "pharmacist." and insert "**pharmacist or pharmacist intern (as defined by IC 25-26-13-2)**".

Page 7, line 25, after "written" insert "**or electronically transmitted**".

Page 13, line 39, delete "computer," and insert "**computer**".

Page 17, line 3, delete "pharmacist" and insert "**pharmacy**".

Page 17, between lines 5 and 6, begin a new paragraph and insert:
"SECTION 19. IC 25-26-14-1 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 1. (a) This chapter applies to any individual, partnership, limited liability company, corporation, or business firm:

- (1) **located within or outside Indiana; and**
- (2) **engaging in the wholesale distribution of legend drugs within in Indiana.**

(b) Except as required by federal law or regulation, the requirements of this chapter do not apply to a manufacturer that is approved by the federal Food and Drug Administration. However, the board may adopt rules concerning manufacturers that the board considers appropriate and necessary.

SECTION 20. IC 25-26-14-1.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 1.5. **As used in this chapter, "adulterated" refers to a drug that:**

- (1) **consists in whole or in part of a filthy, putrid, or**

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decomposed substance;

(2) has been produced, prepared, packed, or held under unsanitary conditions and may have been contaminated or rendered injurious to health;

(3) has been subjected to conditions in the manufacture, processing, packing, or holding of the drug that do not conform to current standards of manufacturing to ensure that the drug is safe for use and possesses the identity, strength, quality, and purity characteristics that the drug is represented to possess;

(4) is contained in a container composed of a poisonous or deleterious substance that may render the drug injurious to health;

(5) bears or contains, for purposes of coloring only, a color additive that is unsafe;

(6) is of a different strength, quality, or purity from the official compendium standard for the drug; or

(7) does not meet the considerations of the federal Food, Drug, and Cosmetic Act.

SECTION 21. IC 25-26-14-1.7 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 1.7. As used in this chapter, "authenticate" means to affirmatively verify before distribution occurs that each transaction that is listed on:**

(1) the pedigree of a drug; and

(2) other accompanying documentation for a drug;

has occurred.

SECTION 22. IC 25-26-14-1.8 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 1.8. As used in this chapter, "authorized distributor" means a wholesale drug distributor with which a manufacturer has established an ongoing relationship to distribute the manufacturer's products. For purposes of this section, an ongoing relationship exists between a wholesale drug distributor, including any affiliated group (as defined in Section 1504 of the Internal Revenue Code) of which the wholesale distributor is a member, and a manufacturer if the wholesale drug distributor:**

(1) has a written agreement currently in effect with the manufacturer evidencing an ongoing relationship;

(2) is listed on the manufacturer's current monthly updated list of authorized distributors; or

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(3) has a verifiable account with the manufacturer and a minimal transaction or volume requirement limit of:

(A) five thousand (5,000) units per company in the previous twelve (12) months; or

(B) twelve (12) purchases at the manufacturer's minimum purchasing requirement per invoice in the previous twelve (12) months.

SECTION 23. IC 25-26-14-4.1 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.1. As used in this chapter, "compendium" refers to:**

(1) the United States Pharmacopoeia;

(2) the Homeopathic Pharmacopoeia of the United States;

(3) the National Formulary;

(4) a drug approved by the federal Food and Drug Administration; or

(5) a supplement to a document specified in subdivision (1), (2), or (3).

SECTION 24. IC 25-26-14-4.2 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.2. As used in this chapter, "contraband" refers to a drug:**

(1) that is counterfeit;

(2) that is stolen;

(3) that is misbranded;

(4) that is obtained by fraud;

(5) that is purchased by a nonprofit institution for the nonprofit institution's own use and placed in commerce in violation of the own use agreement for the drug;

(6) for which a required pedigree does not exist; or

(7) for which a pedigree in existence:

(A) has been forged, counterfeited, or falsely created; or

(B) contains any altered, false, or misrepresented information.

SECTION 25. IC 25-26-14-4.3 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.3. As used in this chapter, "counterfeit" refers to a drug, or the container, seal, or labeling of a drug, that, without authorization, bears the trademark, trade name, or other identifying mark or imprint of a manufacturer, processor, packer, or distributor other than the person that manufactured, processed, packed, or distributed the drug.**

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SECTION 26. IC 25-26-14-4.4 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.4. As used in this chapter, "deliver" means the actual, constructive, or attempted transfer of a drug from one (1) person to another.**

SECTION 27. IC 25-26-14-4.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.5. As used in this chapter, "designated representative" means an individual who:**

- (1) is designated by a wholesale drug distributor;**
- (2) serves as the wholesale drug distributor's responsible individual with the board; and**
- (3) is actively involved in and aware of the actual daily operation of the wholesale drug distributor.**

SECTION 28. IC 25-26-14-4.7 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.7. As used in this chapter, "distribute" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a legend drug, whether by passage of title or physical movement, or both. The term does not include the following:**

- (1) Dispensing or administering a legend drug.**
- (2) Delivering or offering to deliver a legend drug by a common carrier in the usual course of business as a common carrier.**
- (3) The provision of a drug sample to a patient by a:**
 - (A) practitioner;**
 - (B) health care professional acting at the direction and under the supervision of a practitioner; or**
 - (C) hospital's or other health care entity's pharmacy that received the drug sample in accordance with this chapter and other applicable law to administer or dispense and that is acting at the direction of a practitioner;**

licensed to prescribe the legend drug.

SECTION 29. IC 25-26-14-4.9 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.9. As used in this chapter, "drug" means any of the following:**

- (1) Articles recognized in an official compendium and designated by the board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals.**

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(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals.

(3) Articles other than food intended to affect the structure or function of the body of humans or animals.

(4) Articles intended for use as a component of an article specified in subdivision (1), (2), or (3).

The term does not include a device or a device component, part, or accessory.

SECTION 30. IC 25-26-14-6 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 6. As used in this chapter, "health care entity" means any organization or business that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care. **The term does not include a pharmacy or wholesale drug distributor.**

SECTION 31. IC 25-26-14-6.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 6.5. As used in this chapter, "label" means a display of written, printed, or graphic matter on the immediate container of a legend drug.

SECTION 32. IC 25-26-14-6.6 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 6.6. As used in this chapter, "labeling" means labels and other written, printed, or graphic matter:

- (1) on a legend drug or a legend drug's container or wrapper;**
or
- (2) accompanying a legend drug.**

SECTION 33. IC 25-26-14-8.3 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 8.3. As used in this chapter, "misbranded" means that a legend drug's label:

- (1) is false or misleading;**
- (2) does not bear the name and address of the manufacturer, packer, or distributor or does not contain an accurate statement of the quantities of active ingredients of the legend drug;**
- (3) does not show an accurate monograph for the legend drug;**
or
- (4) does not comply with any other requirements of the federal Food, Drug and Cosmetic Act.**

SECTION 34. IC 25-26-14-8.7 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS

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[EFFECTIVE JULY 1, 2005]: **Sec. 8.7.** As used in this chapter, "pedigree" means a statement or record in a written or an electronic form that is approved by the board, that records each distribution of a legend drug from the sale by the manufacturer or, except for drugs on the specified list of susceptible products, from the last authorized distributor of record through acquisition and sale by each wholesale drug distributor, and that includes the following information for each transaction:

(1) The source of the legend drug, including the name and principal address of the seller.

(2) The:

(A) amount and dosage form and strength;

(B) date of purchase;

(C) sales invoice number;

(D) container size;

(E) number of containers;

(F) lot number; and

(G) proprietary and established name;

of the legend drug.

(3) The:

(A) business name and address of each owner of the legend drug; and

(B) legend drug's shipping information, including the name and address of the facility of each person certifying delivery or receipt of the legend drug.

(4) Information that states that the wholesale drug distributor has acted with due diligence as required under this chapter with respect to another wholesale drug distributor from which the wholesale drug distributor purchased or may have purchased the legend drug.

(5) A certification from the designated representative of the wholesale drug distributor that the information contained in the document is true and accurate under penalty of perjury.

SECTION 35. IC 25-26-14-9 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 9.** As used in this chapter, "person" means an individual, a partnership, a business firm, a limited liability company, or a corporation, **or another entity, including a governmental entity.**

SECTION 36. IC 25-26-14-9.2 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 9.2.** As used in this chapter, "practitioner" has the meaning set forth in IC 16-42-19-5.

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SECTION 37. IC 25-26-14-9.3 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION** TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 9.3. As used in this chapter, "repackage" means changing the container, wrapper, quantity, or labeling of a legend drug to further the distribution of the legend drug.**

SECTION 38. IC 25-26-14-10.5 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION** TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 10.5. As used in this chapter, "specified list of susceptible products" means a specific list of legend drugs established by the board, the board's agent, or a third party approved by the board, as:**

- (1) susceptible to adulteration, counterfeiting, or diversion;**
- and**
- (2) posing the potential for a particular public health risk.**

SECTION 39. IC 25-26-14-11 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 11. As used in this chapter, "wholesale distribution" means ~~distribution of~~ to distribute legend drugs to persons other than a consumer or patient. The term does not include:**

- (1) a sale **or transfer** between a division, a subsidiary, a parent, an affiliated, or a related company under the common ownership and control of a corporate entity;
- (2) the purchase or acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for the hospital's or health care entity's own use from the group purchasing organization or from other hospitals or health care entities that are members of the organization;
- (3) the sale of a drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- (4) the sale of a drug among hospitals or other health care entities that are under common control;
- (5) the sale of a drug for emergency medical reasons, including transfers of legend drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, if the gross dollar value of the transfers does not exceed five percent (5%) of the total legend drug sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period;
- (6) the sale of a drug or the dispensing of a drug pursuant to a

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prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives;

(8) the sale of blood and blood components intended for transfusion;

(9) the sale of a drug by a retail pharmacy to a practitioner (as defined in IC 25-26-13-2) for office use, if the gross dollar value of the transfers does not exceed five percent (5%) of the retail pharmacy's total legend drug sales during any twelve (12) consecutive months; or

(10) the sale of a drug by a retail pharmacy that is ending its business and liquidating its inventory to another retail pharmacy;

(11) drug returns by a hospital, health care entity, or charitable institution conducted under 21 CFR 203.23;

(12) the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use; or

(13) the distribution of prescription drugs by the original manufacturer of the finished form of the prescription drug or the distribution of the prescription drugs by a co-promoting partner of the original manufacturer of the finished form of the prescription drug.

SECTION 40. IC 25-26-14-12 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 12. As used in this chapter, "wholesale drug distributor" means a person engaged in wholesale distribution of legend drugs, including:

- (1) manufacturers;
- (2) repackers;
- (3) own-label distributors;
- (4) private-label distributors;
- (5) jobbers;
- (6) brokers;
- (7) warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses;
- (8) independent wholesale drug traders; and
- (9) retail and hospital pharmacies that conduct wholesale distributions.

The term does not include a common carrier or person hired solely to transport prescription drugs.

SECTION 41. IC 25-26-14-14 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 14. (a) ~~After September 14, 1992~~, A person may not engage in wholesale distributions of legend

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drugs without: ~~having~~

(1) **obtaining and maintaining accreditation or certification from an accreditation body approved by the board under subsection (g);**

(2) **obtaining and maintaining** a license ~~from~~ **issued by** the board; and

(3) paying any reasonable fee required by the board.

(b) The board may not issue or renew the license of a wholesale drug distributor that does not comply with this chapter.

(c) The board ~~may~~ **shall** require a separate license for

(1) each facility ~~directly or indirectly owned or operated by the same business in Indiana; or~~

(2) a parent entity with divisions, subsidiaries, or affiliate companies in Indiana when operations are conducted at more than one (1) location and there exists joint ownership and control among all the entities. **or location where wholesale distribution operations are conducted.**

(d) An agent or employee of any licensed wholesale drug distributor does not need a license and may lawfully possess pharmaceutical drugs when acting in the usual course of business or employment.

(e) The issuance of a license under this chapter does not affect tax liability imposed by the department of state revenue or the department of local government finance on any wholesale drug distributor.

(f) The board may adopt rules that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity if:

(1) an out-of-state wholesale drug distributor possesses a valid license granted by another state and the legal standards for licensure in the other state are comparable to the standards under this chapter; and

(2) the other state extends reciprocity to wholesale drug distributors licensed in Indiana.

However, if the requirements for licensure under this chapter are more restrictive than the standards of the other state, the out-of-state wholesale drug distributor must comply with the additional requirements of this chapter to obtain a license under this chapter.

(g) The board shall adopt rules under IC 4-22-2 to approve an accreditation body to:

(1) evaluate a wholesale drug distributor's operations to determine compliance with:

(A) professional standards;

(B) this chapter; and

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- (C) any other applicable law; and
- (2) perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesale drug distributor.

SECTION 42. IC 25-26-14-14.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 14.5. After June 30, 2006, a wholesale drug distributor may not accept or deliver a legend drug without a current, accompanying pedigree.**

SECTION 43. IC 25-26-14-15 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 15. (a) The board shall require the following minimum information from each wholesale drug distributor as part of the license described in section 14 of this chapter and as part of any renewal of such license:**

- (1) The name, full business address, and telephone number of the licensee.
- (2) All trade or business names used by the licensee.
- (3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of legend drugs.
- (4) The type of ownership of operation.
- (5) The name of each owner and operator of the licensee, including:
 - (A) if an individual, the name, **address, Social Security number, and date of birth** of the individual;
 - (B) if a partnership, the name, **address, Social Security number, and date of birth** of each partner, and the name of the partnership **and federal employer identification number**;
 - (C) if a corporation:
 - (i) the name, **address, Social Security number, date of birth**, and title of each corporate officer and director;
 - (ii) the corporate names, ~~and~~ the name of the state of incorporation, **the federal employer identification number, and the name of the parent company, if any; and**
 - (iii) **the name, address, and Social Security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, unless the stock is traded on a major stock exchange and not traded over the counter;**
 - (D) if a limited liability company, the name of each manager and member, the name **and federal identification number** of

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the limited liability company, and the name of the state where organized; and

(E) if a sole proprietorship, the full name, **address, Social Security number, and date of birth** of the sole proprietor and the name **and federal employer identification number** of the business entity.

(6) The name, **address, and telephone number** of the person designated by the licensee as responsible for the operation ~~representative of the facilities:~~ **each facility.**

(7) **Additional information concerning record keeping required under this chapter.**

(b) The board shall require a wholesale drug distributor to post a surety bond of at least one hundred thousand dollars (\$100,000), or an equivalent means of security acceptable to the board, including insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties that may be imposed by the board and any fees and costs that may be incurred by the board and that:

- (1) are related to a license held by the wholesale drug distributor;**
- (2) are authorized under Indiana law; and**
- (3) the wholesale drug distributor fails to pay less than thirty (30) days after the penalties, fees, or costs become final.**

However, a separate surety bond or an equivalent means of security is not required for a separate location or a company of the wholesale drug distributor.

(c) The board may make a claim against a bond or security posted under subsection (b) within one (1) year after the wholesale drug distributor's license is no longer valid or sixty (60) days after the conclusion of:

- (1) an administrative or legal proceeding before or on behalf of the board that involves the wholesale drug distributor and results in penalties, fees, or costs described in subsection (b);**
- or**
- (2) an appeal of a proceeding described in subdivision (1);**

whichever occurs later.

(d) The board shall inspect each facility where wholesale distribution operations are conducted before initial licensure and periodically thereafter in accordance with a schedule determined by the board, but at least one (1) time in each three (3) year period.

(e) A wholesale drug distributor must publicly display or have

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readily available all licenses and the most recent inspection report administered by the board.

~~(b)~~ **(f)** A material change in any information in ~~subsection (a)~~ of this section must be submitted to the board at the time of license renewal or within thirty (30) days from the date of the change, whichever occurs first.

SECTION 44. IC 25-26-14-15.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 15.5. (a) A wholesale drug distributor that is an authorized distributor of a manufacturer is not considered to be an authorized distributor of the manufacturer under this chapter unless:**

- (1) the manufacturer files the manufacturer's monthly updated list of authorized distributors with the board;**
- (2) the list is available from the manufacturer upon request or on the Internet; and**
- (3) the manufacturer notifies the board of any change to the list within ten (10) days after the change.**

(b) The board shall make available on the board's Internet web site a manufacturer's list of authorized distributors filed as described in subsection (a).

SECTION 45. IC 25-26-14-16 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 16. (a) In reviewing, for purposes of licensure or renewal of a license under this chapter, the qualifications of persons who engage in wholesale distribution of legend drugs within in Indiana, the board shall consider the following factors:**

- ~~(1) A conviction of the applicant relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances. **finding by the board that the applicant has:**~~
 - (A) violated a law; or**
 - (B) been disciplined by a regulatory agency for violating a law;****related to drug distribution in any state.**
- ~~(2) A **felony criminal** conviction of the applicant.~~
- ~~(3) The applicant's past experience in the manufacture or distribution of legend drugs, including controlled substances.~~
- ~~(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution.~~
- ~~(5) Suspension or revocation **of any license held by the applicant or the applicant's owner or the imposition of**~~

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sanctions against the applicant or the applicant's owner by the federal or a state **or local** government ~~of any license held by the applicant~~ for the manufacture or distribution of any drugs, including controlled substances.

(6) Compliance with licensing requirements under previously granted licenses.

(7) Compliance with requirements to maintain and make available to the board or to federal, state, or local law enforcement officials those records required under this chapter.

(8) Any other factors or qualifications the board considers relevant to the public health and safety, including whether the granting of the license would not be in the public interest.

(b) In reviewing an application for licensure or renewal of a license under this chapter, the board shall consider the results of a national criminal history background check (as defined in IC 10-13-3-12) for:

- (1) the applicant;
- (2) all personnel involved in the operations of the wholesale drug distributor;
- (3) the most senior individual responsible for facility operations, purchasing, and inventory control, and the individual to whom the senior individual reports;
- (4) company officers;
- (5) key management personnel;
- (6) principals; and
- (7) owners with at least a ten percent (10%) interest in the wholesale drug distributor, if the wholesale drug distributor is a nonpublicly held company.

The national criminal history background check must be conducted at the applicant's expense and must include all states of residence since the applicant became eighteen (18) years of age.

(c) An applicant shall provide and attest to:

- (1) an affirmation that the applicant has not been involved in or convicted of any criminal or prohibited acts; or
- (2) a statement providing a complete disclosure of the applicant's past criminal convictions and violations of state and federal laws;

regarding drugs.

SECTION 46. IC 25-26-14-16.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 16.5. (a) A wholesale drug distributor shall designate in writing on a form prescribed by the**

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board a designated representative for each of the wholesale drug distributor's facilities licensed under this chapter.

(b) A designated representative shall submit to the board an application prescribed by the board and provide to the board the following:

(1) A set of the designated representative's fingerprints, under procedures specified by the board and according to requirements of the state police department under IC 10-13-3-38.5, with the payment of the amount equal to the costs of a national criminal history background check (as defined in IC 10-13-3-12) of the designated representative to be obtained by the state police department.

(2) The date and place of birth of the designated representative.

(3) A list of the occupations, positions of employment, and offices held by the designated representative during the immediately preceding seven (7) years, including the principal business and address of the organization with which the occupation, position, or office was associated.

(4) A statement concerning whether the designated representative, during the immediately preceding seven (7) years, has been temporarily or permanently enjoined by a court from violating a state or federal law regulating the possession, control, or distribution of drugs, including details of related events.

(5) A description of any involvement by the designated representative with a business that:

(A) manufactured, administered, prescribed, distributed, or stored drugs; and

(B) was named as a party in a lawsuit;

during the immediately preceding seven (7) years, including investments other than the ownership of stock in a publicly traded company or mutual fund.

(6) A description of any criminal offense of which the designated representative has been convicted, regardless of whether adjudication of guilt was withheld or whether the designated representative pleaded nolo contendere. If the designated representative indicates that a criminal conviction is under appeal, the designated representative shall submit to the board:

(A) a copy of the notice of appeal; and

(B) a copy of the final written order of disposition.

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(7) A photograph of the designated representative taken within the immediately preceding thirty (30) days under procedures specified by the board.

(8) A list of the name, address, occupation, and date and place of birth of each member of the designated representative's immediate family, including the designated representative's spouse, children, parents, and siblings, and the spouses of the designated representative's children and siblings. Information collected under this subdivision is confidential.

(9) Any other information required by the board.

(c) A designated representative must have at least two (2) years of verifiable full-time managerial or supervisory experience in a pharmacy or with a wholesale drug distributor licensed under this chapter or in another state. The designated representative's responsibilities must have included record keeping, storage, and shipment of legend drugs.

(d) A designated representative shall not serve as the designated representative for more than one (1) wholesale drug distributor facility at any one (1) time.

(e) A designated representative shall be actively involved and aware of the actual daily operations of the wholesale drug distributor as follows:

(1) Be employed full time in a managerial position by the wholesale drug distributor.

(2) Be physically present at the wholesale drug distributor's facility during normal business hours, except when absent due to illness, family illness or death, scheduled vacation, or another authorized absence.

(3) Be aware of and knowledgeable about all policies and procedures pertaining to the operations of the wholesale drug distributor.

(f) A designated representative must complete continuing education programs specified by the board regarding state and federal law relevant to the distribution, handling, and storage of legend drugs.

SECTION 47. IC 25-26-14-16.6 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 16.6. (a) A wholesale drug distributor that:

- (1) is licensed under this chapter;
- (2) is located outside Indiana; and
- (3) distributes legend drugs in Indiana;

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shall designate an agent in Indiana for service of process.

(b) A wholesale drug distributor that does not designate an agent under subsection (a) is considered to have designated the secretary of state to be the wholesale drug distributor's true and lawful attorney, upon whom legal process may be served in an action or a proceeding against the wholesale drug distributor arising from the wholesale drug distributor's wholesale distribution operations.

(c) The board shall mail a copy of any service of process to a wholesale drug distributor by certified mail, return receipt requested, postage prepaid, at the address designated by the wholesale drug distributor on the application for licensure submitted under this chapter.

(d) Service of process on the secretary of state is sufficient in an action or a proceeding against a wholesale drug distributor that is not licensed under this chapter.

SECTION 48. IC 25-26-14-17 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 17. As a condition for receiving and retaining any a wholesale drug distributor license issued under to this chapter, each an applicant must satisfy the board that the applicant has and will continuously maintain the following:

(1) Acceptable storage and handling conditions and facilities standards for each facility at which legend drugs are received, stored, warehoused, handled, held, offered, marketed, or displayed, or from which legend drugs are transported, including:

(A) suitable construction of the facility and appropriate monitoring equipment to ensure that legend drugs in the facility are maintained in accordance with labeling or in compliance with official compendium standards;

(B) suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;

(C) adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(D) a quarantine area for separate storage of legend drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, suspected counterfeit, otherwise unfit for distribution, or contained in immediate or sealed secondary containers that have been opened;

(E) maintenance of the facility in a clean and orderly

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condition;

(F) maintenance of the facility in a commercial, nonresidential building; and

(G) freedom of the facility from infestation.

(2) Security of each facility from unauthorized entry as follows:

(A) Entry into areas where legend drugs are held is limited to authorized personnel.

(B) Each facility is equipped with a security system that includes:

~~(A)~~ (i) an after hours central alarm or a comparable entry detection capability;

~~(B)~~ (ii) restricted premises access;

~~(C)~~ (iii) adequate outside perimeter lighting; and

~~(D)~~ (iv) safeguards against theft and diversion, including employee theft and theft or diversion facilitated or hidden by tampering with computers or electronic records; and (v) a means of protecting the integrity and confidentiality of data and documents and of making the data and documents readily available to the board and other state and federal law enforcement officials.

(3) A reasonable system of record keeping that as follows:

(A) The system describes all the wholesale distributor's activities governed by this chapter for the two ~~(2)~~ three (3) year period after the disposition of each product and all records are maintained for at least three (3) years after disposition of the legend drug to which the record applies.

(B) The system is reasonably accessible as determined by board rules in any inspection authorized by the board.

(C) The system provides a means to establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of all legend drugs, including the following:

(i) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is an authorized distributor, a pedigree for each distributed legend drug that is on the specified list of susceptible products or that leaves the normal distribution chain of custody from the manufacturer to a wholesale drug distributor, to a pharmacy, and to the patient or the patient's agent.

(ii) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is not an

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authorized distributor, a pedigree for each distributed legend drug.

(iii) After January 1, 2007, at the board's discretion, for each legend drug received and distributed by the wholesale drug distributor, an electronic pedigree developed in accordance with standards and requirements of the board to authenticate, track, and trace legend drugs. The standards and requirements of the board may indicate the information required to be part of the electronic pedigree.

(iv) Dates of receipt and distribution or other disposition of the legend drugs by the wholesale drug distributor.

(v) Availability for inspection and photocopying by any authorized official of a local, state, or federal governmental agency for three (3) years after the creation date of the inventories and records.

(D) Onsite electronic inventories and records are immediately available for inspection. Records kept at a central location apart from the inspection site and not electronically retrievable are available for inspection within two (2) working days after a request by an authorized official of a local, state, or federal governmental agency.

(E) The system maintains an ongoing list of persons with whom the wholesale drug distributor does business.

(F) The system provides for reporting counterfeit or suspected counterfeit legend drugs or counterfeiting or suspected counterfeiting activities to the board and federal Food and Drug Administration.

(G) The system provides for mandatory reporting of significant shortages or losses of legend drugs to the board and federal Food and Drug Administration if diversion is known or suspected.

(4) Written policies and procedures to which the wholesale drug distributor adheres for the receipt, security, storage, inventory, transport, shipping, and distribution of legend drugs, and that assure reasonable wholesale distributor preparation for, protection against, and handling of any facility security or operation problems, including the following:

(A) ~~those~~ Facility security or operation problems caused by natural disaster or government emergency.

(B) Correction of inventory inaccuracies. ~~or~~

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(C) Product shipping and receiving **problems.**

~~(D)~~ (D) **Quarantine and return to the manufacturer or destruction in accordance with state and federal law of all outdated product products and outdated or expired legend drugs, including appropriate documentation and witnessing.**

~~(E)~~ (E) **Appropriate disposition of returned goods. and**

~~(F)~~ (F) **Product recalls.**

(G) **Identifying, recording, and reporting losses or thefts.**

(H) **Implementation and maintenance of a continuous quality improvement system.**

(I) **Recalls and withdrawals of legend drugs due to:**

(i) **an action initiated by the federal Food and Drug Administration or another federal, state, or local governmental agency;**

(ii) **a volunteer action by the manufacturer to remove defective or potentially defective legend drugs from the market; or**

(iii) **an action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design.**

(J) **Disposition and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging are not used in counterfeiting activities, including necessary documentation and witnessing in accordance with state and federal law.**

(K) **Investigation of discrepancies in the inventory involving counterfeit, suspected counterfeit, contraband, or suspected contraband legend drugs and reporting of discrepancies within three (3) business days to the board and any other appropriate state or federal governmental agency.**

(L) **Reporting of criminal or suspected criminal activities involving the inventory of legend drugs to the board within three (3) business days.**

(M) **Conducting for cause authentication and random authentication as required under sections 17.2, 17.3, and 17.8 of this chapter.**

(5) **Written policies and procedures and sufficient inspection procedures for all incoming and outgoing product shipments, including the following:**

(A) **Upon receipt, visual examination of each shipping**

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container in a manner adequate to identify the legend drugs in the container and to determine whether the legend drugs may be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution.

(B) Upon receipt, review of records by the wholesale drug distributor for the acquisition of legend drugs for accuracy and completeness, considering the:

- (i) total facts and circumstances surrounding each transaction involving the legend drugs; and
- (ii) wholesale drug distributors involved.

(C) Quarantine of a legend drug considered to be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution until:

- (i) examination and a determination that the legend drug is not outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution; or
- (ii) the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.

(D) Written policies and procedures to ensure that a legend drug that was:

- (i) ordered in error or in excess of need by the wholesale drug distributor;
- (ii) identified within three (3) business days after receipt as ordered in error or in excess of need; and
- (iii) maintained such that the legend drug's integrity has not been compromised;

may be returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired if the appropriate documentation is completed and necessary notations are made to a required pedigree.

(E) Written policies and procedures to ensure that if the wholesale drug distributor determines that a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired

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within three (3) business days.

(F) Written policies and procedures to ensure that if the immediate or sealed outer or secondary container or labeling of a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor:

(i) quarantines the legend drug until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired; and

(ii) provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired within three (3) business days.

(G) Written policies and procedures to ensure that a legend drug that has been opened or used, but is not adulterated, misbranded, counterfeit, or suspected counterfeit, is identified as such and quarantined until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.

(H) Written policies and procedures to ensure that:

(i) a legend drug that will be returned to a manufacturer or wholesale drug distributor is kept under proper conditions for storage, handling, transport, and shipment before the return; and

(ii) documentation showing that proper conditions were maintained is provided to the manufacturer or wholesale drug distributor to which the legend drug is returned.

(I) Inspection of each outgoing shipment for identity of the legend drugs and to ensure that the legend drugs have not been damaged in storage or held under improper conditions.

(J) Written policies and procedures to ensure that if conditions under which a legend drug has been returned to the wholesale drug distributor cast doubt on the legend drug's safety, identity, strength, quality, or purity, the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired unless examination, testing, or other

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investigation proves that the legend drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a legend drug has been returned cast doubt on the legend drug's safety, identity, strength, quality, or purity, the wholesale drug distributor considers the conditions under which the legend drug has been held, stored, or shipped before or during the legend drug's return and the condition of the legend drug and the legend drug's container, carton, or labeling upon receipt of the returned legend drug.

(K) Written policies and procedures to ensure that contraband, counterfeit, or suspected counterfeit legend drugs, other evidence of criminal activity, and accompanying documentation are retained until a disposition is authorized by the board and the federal Food and Drug Administration.

(L) Written policies and procedures to ensure that any shipping, immediate, or sealed outer or secondary container or labeling, and accompanying documentation, suspected of or determined to be counterfeit or fraudulent, are retained until a disposition is authorized by the board and federal Food and Drug Administration.

(6) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

(7) Written policies and procedures to provide for the secure and confidential storage of information with restricted access and to protect the integrity and confidentiality of the information.

(8) A pedigree as required under this chapter, including an electronic pedigree developed in accordance with standards and requirements of the board under subdivision (3)(C)(iii).

(9) Appropriate inventory management and control systems to:

(A) prevent; and

(B) allow detection and documentation of; theft, counterfeiting, or diversion of legend drugs.

(10) If the wholesale drug distributor is involved in the distribution of controlled substances, registration with the federal Drug Enforcement Administration and board and compliance with all laws related to the storage, handling, transport, shipment, and distribution of controlled

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substances.

(11) Isolation of controlled substances from noncontrolled substances and storage of the controlled substances in a secure area in accordance with federal Drug Enforcement Administration security requirements and standards.

(12) Technology and equipment that allow the wholesale drug distributor to authenticate, track, and trace legend drugs. The technology and equipment meets standards set by the board and is used as required by the board to conduct for cause and random tracking, tracing, and authentication of legend drugs.

(13) Employment, training, and documentation of the training concerning the proper use of the technology and equipment required under subdivision (12).

(14) Packaging operations in accordance with an official compendium allowing the identification of a compromise in the integrity of the legend drugs due to tampering or adverse storage conditions.

SECTION 49. IC 25-26-14-17.2 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 17.2. (a) A wholesale drug distributor that purchases legend drugs from another wholesale drug distributor and has reason to believe that a legend drug purchased from the other wholesale drug distributor is counterfeit, suspected counterfeit, misbranded, or adulterated shall conduct a for cause authentication of each distribution of the legend drug back to the manufacturer.

(b) A wholesale drug distributor that has engaged in the distribution of a legend drug for which a purchasing wholesale drug distributor conducts a for cause authentication under subsection (a) shall provide, upon request, detailed information regarding the distribution of the legend drug, including the:

- (1) date of purchase of the legend drug;
- (2) lot number of the legend drug;
- (3) sales invoice number of the legend drug; and
- (4) contact information, including name, address, telephone number, and electronic mail address of the wholesale drug distributor that sold the legend drug.

(c) If a wholesale drug distributor conducts a for cause authentication under subsection (a) and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more

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than ten (10) business days after completing the attempted authentication.

(d) If a wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (a), the wholesale drug distributor shall maintain records of the authentication for three (3) years and shall produce the records for the board and the federal Food and Drug Administration upon request.

SECTION 50. IC 25-26-14-17.3 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 17.3. (a) A wholesale drug distributor that purchases legend drugs from another wholesale drug distributor shall, at least annually, conduct a random authentication of a required pedigree on at least ten percent (10%) of sales units of wholesale distributions of legend drugs purchased from other wholesale drug distributors.

(b) If a wholesale drug distributor purchases from another wholesale drug distributor a legend drug that is on the specified list of susceptible products, the wholesale drug distributor shall, at least quarterly, conduct a random authentication of a required pedigree on at least ninety percent (90%) of sales units of distributions of legend drugs that are on the specified list of susceptible products and that were purchased from other wholesale drug distributors.

(c) A wholesale drug distributor from whom another wholesale drug distributor purchases legend drugs shall cooperate with random authentications of pedigrees described in this section and provide requested information in a timely manner.

(d) If a wholesale drug distributor conducts a random authentication under this section and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

SECTION 51. IC 25-26-14-17.8 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 17.8. (a) A wholesale drug distributor licensed under this chapter that purchases legend drugs from a wholesale drug distributor that is not licensed under this chapter shall act with due diligence as required under this section.

(b) Before the initial purchase of legend drugs from the

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unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall obtain the following information from the unlicensed wholesale drug distributor:

- (1) A list of states in which the unlicensed wholesale drug distributor is licensed.
- (2) A list of states into which the unlicensed wholesale drug distributor ships legend drugs.
- (3) Copies of all state and federal regulatory licenses and registrations held by the unlicensed wholesale drug distributor.
- (4) The unlicensed wholesale drug distributor's most recent facility inspection reports.
- (5) Information regarding general and product liability insurance maintained by the unlicensed wholesale drug distributor, including copies of relevant policies.
- (6) A list of other names under which the unlicensed wholesale drug distributor does business or has been previously known.
- (7) A list of corporate officers and managerial employees of the unlicensed wholesale drug distributor.
- (8) A list of all owners of the unlicensed wholesale drug distributor that own more than ten percent (10%) of the unlicensed wholesale drug distributor, unless the unlicensed wholesale drug distributor is publicly traded.
- (9) A list of all disciplinary actions taken against the unlicensed wholesale drug distributor by state and federal agencies.
- (10) A description, including the address, dimensions, and other relevant information, of each facility used by the unlicensed wholesale drug distributor for legend drug storage and distribution.
- (11) A description of legend drug import and export activities of the unlicensed wholesale drug distributor.
- (12) A description of the unlicensed wholesale drug distributor's procedures to ensure compliance with this chapter.
- (13) A statement:
 - (A) as to whether; and
 - (B) of the identity of each manufacturer for which; the unlicensed wholesale drug distributor is an authorized distributor.
- (c) Before the initial purchase of legend drugs from an unlicensed wholesale drug distributor, the licensed wholesale drug

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distributor shall:

(1) request that the board obtain and consider the results of a national criminal history background check (as defined in IC 10-13-3-12) through the state police department of all individuals associated with the unlicensed wholesale drug distributor as specified for licensure of a wholesale drug distributor under section 16(b) of this chapter; and

(2) verify the unlicensed wholesale drug distributor's status as an authorized distributor, if applicable.

(d) If an unlicensed wholesale drug distributor's facility has not been inspected by the board or the board's agent within three (3) years after a contemplated purchase described in subsection (a), the licensed wholesale drug distributor shall conduct an inspection of the unlicensed wholesale drug distributor's facility:

(1) before the initial purchase of legend drugs from the unlicensed wholesale drug distributor; and

(2) at least once every three (3) years unless the unlicensed wholesale drug distributor's facility has been inspected by the board, or the board's agent, during the same period;

to ensure compliance with applicable laws and regulations relating to the storage and handling of legend drugs. A third party may be engaged to conduct the site inspection on behalf of the licensed wholesale drug distributor.

(e) At least annually, a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall ensure that the unlicensed wholesale drug distributor maintains a record keeping system that meets the requirements of section 17(3) of this chapter.

(f) If a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor has reason to believe that a legend drug purchased from the unlicensed wholesale drug distributor is misbranded, adulterated, counterfeit, or suspected counterfeit, the licensed wholesale drug distributor shall conduct a for cause authentication of each distribution of the legend drug back to the manufacturer.

(g) An unlicensed wholesale drug distributor that has engaged in the distribution of a legend drug for which a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) shall provide, upon request, detailed information regarding the distribution of the legend drug, including the:

(1) date of purchase of the legend drug;

(2) lot number of the legend drug;

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- (3) sales invoice number of the legend drug; and**
- (4) contact information, including name, address, telephone number, and any electronic mail address of the unlicensed wholesale drug distributor that sold the legend drug.**

(h) If a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) and is unable to authenticate each distribution of the legend drug, the licensed wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration within ten (10) business days after completing the attempted authentication.

(i) If a licensed wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (f), the licensed wholesale drug distributor shall maintain records of the authentication for three (3) years and shall provide the records to the board upon request.

(j) A licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall, at least annually, conduct random authentications of required pedigrees on at least ten percent (10%) of sales units of distributions of legend drugs that were purchased from unlicensed wholesale drug distributors.

(k) A licensed wholesale drug distributor that has purchased a legend drug that is on the specified list of susceptible products shall, at least quarterly, conduct random authentications of required pedigrees on at least ninety percent (90%) of sales units of distributions of legend drugs that:

- (1) are on the specified list of susceptible products; and**
- (2) were purchased from unlicensed wholesale drug distributors.**

(l) An unlicensed wholesale drug distributor from which a licensed wholesale drug distributor has purchased legend drugs shall cooperate with the random authentications of pedigrees under this section and provide requested information in a timely manner.

(m) If a wholesale drug distributor conducts a random authentication under subsection (j) or (k) and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

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SECTION 52. IC 25-26-14-17.9 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 17.9. A wholesale drug distributor licensed under this chapter may not use a trade name or business name identical to a trade name or business name used by another wholesale drug distributor licensed under this chapter.**

SECTION 53. IC 25-26-14-20 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 20. (a)** A person employed in wholesale distribution must have appropriate education or experience to assume responsibility for positions related to compliance with licensing requirements.

(b) Before employing a person to be engaged in the operation and handling of legend drugs, a wholesale drug distributor shall request that the board obtain and consider the results of a national criminal history background check (as defined in IC 10-13-3-12) through the state police department for the person.

SECTION 54. IC 25-26-14-21.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 21.5. (a)** A person may not perform, cause the performance of, or aid the performance of the following:

- (1) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a legend drug that is adulterated, misbranded, counterfeit, suspected counterfeit, or is otherwise unfit for distribution.**
- (2) The adulteration, misbranding, or counterfeiting of a legend drug.**
- (3) The receipt of a legend drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit, and the delivery or proffered delivery of the legend drug for pay or otherwise.**
- (4) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a legend drug or the commission of another act with respect to a legend drug that results in the legend drug being misbranded.**
- (5) Forging, counterfeiting, simulating, or falsely representing a legend drug using a mark, stamp, tag, label, or other identification device without the authorization of the manufacturer.**
- (6) The purchase or receipt of a legend drug from a person that is not licensed to distribute legend drugs to the purchaser or recipient.**

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(7) The sale or transfer of a legend drug to a person that is not authorized under the law of the jurisdiction in which the person receives the legend drug to purchase or receive legend drugs from the person selling or transferring the legend drug.

(8) Failure to maintain or provide records as required under this chapter.

(9) Providing the board, a representative of the board, or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to this chapter.

(10) The wholesale distribution of a legend drug that was:

(A) purchased by a public or private hospital or other health care entity;

(B) donated or supplied at a reduced price to a charitable organization; or

(C) stolen or obtained by fraud or deceit.

(11) Obtaining or attempting to obtain a legend drug by fraud, deceit, misrepresentation, or engaging in fraud, deceit, or misrepresentation in the distribution of a legend drug.

(12) Failure to obtain, authenticate, or provide a required pedigree.

(13) The receipt of a legend drug through wholesale distribution without first receiving a required pedigree attested to as accurate and complete by the wholesale drug distributor.

(14) Distributing a legend drug that was previously dispensed by a retail pharmacy or distributed by a practitioner.

(15) Failure to report an act prohibited by this section.

(b) The board may impose the following sanctions if, after a hearing under IC 4-21.5-3, the board finds that a person has violated subsection (a):

(1) Revoke the wholesale drug distributor's license issued under this chapter if the person is a wholesale drug distributor.

(2) Assess a civil penalty against the person. A civil penalty assessed under this subdivision may not be more than ten thousand dollars (\$10,000) per violation.

SECTION 55. IC 25-26-14-26 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 26. (a) A person that who knowingly or intentionally engages in the wholesale distribution of a legend drug without a license issued under this chapter commits a Class D felony.

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(b) A person who engages in the wholesale distribution of a legend drug and:

(1) who, with intent to defraud or deceive:

(A) fails to obtain or deliver to another person a complete and accurate required pedigree concerning a legend drug before:

(i) obtaining the legend drug from another person; or

(ii) transferring the legend drug to another person; or

(B) falsely swears or certifies that the person has authenticated any documents related to the wholesale distribution of legend drugs;

(2) who knowingly or intentionally:

(A) destroys, alters, conceals, or fails to maintain a complete and accurate required pedigree concerning a legend drug in the person's possession;

(B) purchases or receives legend drugs from a person not authorized to distribute legend drugs in wholesale distribution;

(C) sells, barters, brokers, or transfers a legend drug to a person not authorized to purchase the legend drug in the jurisdiction in which the person receives the legend drug in a wholesale distribution;

(D) forges, counterfeits, or falsely creates a pedigree;

(E) falsely represents a factual matter contained in a pedigree; or

(F) fails to record material information required to be recorded in a pedigree; or

(3) who:

(A) possesses a required pedigree concerning a legend drug;

(B) knowingly or intentionally fails to authenticate the matters contained in the pedigree as required; and

(C) distributes or attempts to further distribute the legend drug;

commits a Class D felony.

SECTION 56. IC 25-26-14-27 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 27. A wholesale drug distributor that fails to comply with the conditions **and requirements** described in section 17, **17.2, 17.3, 17.8, 17.9, or 20** of this chapter commits a Class D felony."

Page 18, between lines 13 and 14, begin a new paragraph and insert:

"SECTION 60. IC 34-24-1-1 IS AMENDED TO READ AS

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FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 1. (a) The following may be seized:

(1) All vehicles (as defined by IC 35-41-1), if they are used or are intended for use by the person or persons in possession of them to transport or in any manner to facilitate the transportation of the following:

(A) A controlled substance for the purpose of committing, attempting to commit, or conspiring to commit any of the following:

(i) Dealing in or manufacturing cocaine, a narcotic drug, or methamphetamine (IC 35-48-4-1).

(ii) Dealing in a schedule I, II, or III controlled substance (IC 35-48-4-2).

(iii) Dealing in a schedule IV controlled substance (IC 35-48-4-3).

(iv) Dealing in a schedule V controlled substance (IC 35-48-4-4).

(v) Dealing in a counterfeit substance (IC 35-48-4-5).

(vi) Possession of cocaine, a narcotic drug, or methamphetamine (IC 35-48-4-6).

(vii) Dealing in paraphernalia (IC 35-48-4-8.5).

(viii) Dealing in marijuana, hash oil, or hashish (IC 35-48-4-10).

(B) Any stolen (IC 35-43-4-2) or converted property (IC 35-43-4-3) if the retail or repurchase value of that property is one hundred dollars (\$100) or more.

(C) Any hazardous waste in violation of IC 13-30-6-6.

(D) A bomb (as defined in IC 35-41-1-4.3) or weapon of mass destruction (as defined in IC 35-41-1-29.4) used to commit, used in an attempt to commit, or used in a conspiracy to commit an offense under IC 35-47 as part of or in furtherance of an act of terrorism (as defined by IC 35-41-1-26.5).

(2) All money, negotiable instruments, securities, weapons, communications devices, or any property used to commit, used in an attempt to commit, or used in a conspiracy to commit an offense under IC 35-47 as part of or in furtherance of an act of terrorism or commonly used as consideration for a violation of IC 35-48-4 (other than items subject to forfeiture under IC 16-42-20-5 or IC 16-6-8.5-5.1 before its repeal):

(A) furnished or intended to be furnished by any person in exchange for an act that is in violation of a criminal statute;

(B) used to facilitate any violation of a criminal statute; or

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- (C) traceable as proceeds of the violation of a criminal statute.
- (3) Any portion of real or personal property purchased with money that is traceable as a proceed of a violation of a criminal statute.
- (4) A vehicle that is used by a person to:
- (A) commit, attempt to commit, or conspire to commit;
 - (B) facilitate the commission of; or
 - (C) escape from the commission of;
- murder (IC 35-42-1-1), kidnapping (IC 35-42-3-2), criminal confinement (IC 35-42-3-3), rape (IC 35-42-4-1), child molesting (IC 35-42-4-3), or child exploitation (IC 35-42-4-4), or an offense under IC 35-47 as part of or in furtherance of an act of terrorism.
- (5) Real property owned by a person who uses it to commit any of the following as a Class A felony, a Class B felony, or a Class C felony:
- (A) Dealing in or manufacturing cocaine, a narcotic drug, or methamphetamine (IC 35-48-4-1).
 - (B) Dealing in a schedule I, II, or III controlled substance (IC 35-48-4-2).
 - (C) Dealing in a schedule IV controlled substance (IC 35-48-4-3).
 - (D) Dealing in marijuana, hash oil, or hashish (IC 35-48-4-10).
- (6) Equipment and recordings used by a person to commit fraud under IC 35-43-5-4(11).
- (7) Recordings sold, rented, transported, or possessed by a person in violation of IC 24-4-10.
- (8) Property (as defined by IC 35-41-1-23) or an enterprise (as defined by IC 35-45-6-1) that is the object of a corrupt business influence violation (IC 35-45-6-2).
- (9) Unlawful telecommunications devices (as defined in IC 35-45-13-6) and plans, instructions, or publications used to commit an offense under IC 35-45-13.
- (10) Any equipment used or intended for use in preparing, photographing, recording, videotaping, digitizing, printing, copying, or disseminating matter in violation of IC 35-42-4-4.
- (11) Destructive devices used, possessed, transported, or sold in violation of IC 35-47.5.
- (12) Cigarettes that are sold in violation of IC 24-3-5.2, cigarettes that a person attempts to sell in violation of IC 24-3-5.2, and other personal property owned and used by a person to facilitate a violation of IC 24-3-5.2.
- (13) Tobacco products that are sold in violation of IC 24-3-5,

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tobacco products that a person attempts to sell in violation of IC 24-3-5, and other personal property owned and used by a person to facilitate a violation of IC 24-3-5.

(14) If a person is convicted of an offense specified in IC 25-26-14-26(b) or IC 35-43-10, the following real or personal property:

(A) Property used or intended to be used to commit, facilitate, or promote the commission of the offense.

(B) Property constituting, derived from, or traceable to the gross proceeds that the person obtained directly or indirectly as a result of the offense.

(b) A vehicle used by any person as a common or contract carrier in the transaction of business as a common or contract carrier is not subject to seizure under this section, unless it can be proven by a preponderance of the evidence that the owner of the vehicle knowingly permitted the vehicle to be used to engage in conduct that subjects it to seizure under subsection (a).

(c) Equipment under subsection (a)(10) may not be seized unless it can be proven by a preponderance of the evidence that the owner of the equipment knowingly permitted the equipment to be used to engage in conduct that subjects it to seizure under subsection (a)(10).

(d) Money, negotiable instruments, securities, weapons, communications devices, or any property commonly used as consideration for a violation of IC 35-48-4 found near or on a person who is committing, attempting to commit, or conspiring to commit any of the following offenses shall be admitted into evidence in an action under this chapter as prima facie evidence that the money, negotiable instrument, security, or other thing of value is property that has been used or was to have been used to facilitate the violation of a criminal statute or is the proceeds of the violation of a criminal statute:

- (1) IC 35-48-4-1 (dealing in or manufacturing cocaine, a narcotic drug, or methamphetamine).
- (2) IC 35-48-4-2 (dealing in a schedule I, II, or III controlled substance).
- (3) IC 35-48-4-3 (dealing in a schedule IV controlled substance).
- (4) IC 35-48-4-4 (dealing in a schedule V controlled substance) as a Class B felony.
- (5) IC 35-48-4-6 (possession of cocaine, a narcotic drug, or methamphetamine) as a Class A felony, Class B felony, or Class C felony.
- (6) IC 35-48-4-10 (dealing in marijuana, hash oil, or hashish) as a Class C felony.

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SECTION 61. IC 35-43-10 IS ADDED TO THE INDIANA CODE AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]:

Chapter 10. Legend Drug Deception

Sec. 1. The definitions in IC 25-26-14 apply throughout this chapter.

Sec. 2. A person who knowingly or intentionally:

- (1) possesses a contraband legend drug;**
- (2) sells, delivers, or possesses with intent to sell or deliver a contraband legend drug;**
- (3) forges, counterfeits, or falsely creates a label for a legend drug or falsely represents a factual matter contained on a label of a legend drug; or**
- (4) manufactures, purchases, sells, delivers, brings into Indiana, or possesses a contraband legend drug;**

commits legend drug deception, a Class D felony.

Sec. 3. A person:

- (1) who knowingly or intentionally manufactures, purchases, sells, delivers, brings into Indiana, or possesses a contraband legend drug; and**
- (2) whose act under subdivision (1) results in the death of an individual;**

commits legend drug deception resulting in death, a Class A felony."

Page 18, after line 42, begin a new paragraph and insert:

"SECTION 63. IC 35-48-7-5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 5. As used in this chapter, "identification number" refers to **the following:**

(1) The unique number contained on any of the following:

- ~~(1)~~ **(A)** A valid driver's license of a recipient or a recipient's representative issued under Indiana law or the law of any other state.
- ~~(2)~~ **(B)** A recipient's or a recipient representative's valid military identification card.
- ~~(3)~~ **(C)** A valid identification card of a recipient or a recipient's representative issued by:
 - ~~(A)~~ **(i)** the bureau of motor vehicles and described in IC 9-24-16-3; or
 - ~~(B)~~ **(ii)** any other state and that is similar to the identification card issued by the bureau of motor vehicles.
- ~~(4)~~ **(D)** If the recipient is an animal:
 - ~~(A)~~ **(i)** the valid driver's license issued under Indiana law or

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the law of any other state;
~~(B)~~ (ii) the valid military identification card; or
~~(C)~~ (iii) the valid identification card issued by the bureau of motor vehicles and described in IC 9-24-16-3 or a valid identification card of similar description that is issued by any other state;

of the animal's owner.

(2) The identification number or phrase designated by the central repository.

SECTION 64. IC 35-48-7-8 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 8. The advisory committee shall provide for a controlled substance prescription monitoring program that includes the following components:

(1) Each time a controlled substance designated by the advisory committee under IC 35-48-2-5 through IC 35-48-2-10 is dispensed, the dispenser shall transmit to the central repository the following information:

(A) The recipient's name.

(B) The recipient's or the recipient representative's identification number **or the identification number or phrase designated by the central repository.**

(C) The recipient's date of birth.

(D) The national drug code number of the controlled substance dispensed.

(E) The date the controlled substance is dispensed.

(F) The quantity of the controlled substance dispensed.

(G) The number of days of supply dispensed.

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

(I) 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.

(2) The information required to be transmitted under this section must be transmitted not more than fifteen (15) days after the date on which a controlled substance is dispensed.

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

(A) an electronic device compatible with the receiving device of the central repository;

(B) a computer diskette;

(C) a magnetic tape; or

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(D) a pharmacy universal claim form; that meets specifications prescribed by the advisory committee.

(4) The advisory committee may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the advisory committee may not apply such a requirement to prescriptions filled at a pharmacy with a Type 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 committee may not require multiple copy prescription forms and serially numbered prescription forms for any prescriptions written. The committee may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be jointly approved by the committee and by the Indiana board of pharmacy established by IC 25-26-13-3.

(5) The costs of the program.

SECTION 65. [EFFECTIVE JULY 1, 2005] (a) IC 25-26-14, as amended by this act, applies:

- (1) after June 30, 2005, for an initial license issued under IC 25-26-14, as amended by this act; and**
- (2) on the first expiration date occurring after December 31, 2005, for renewal of a license issued under IC 25-26-14, before amendment by this act.**

(b) The Indiana board of pharmacy established by IC 25-26-13-3 may establish an electronic pedigree pilot program to authenticate, track, and trace legend drugs. The pilot program must include participation of drug manufacturers, wholesale drug distributors, and pharmacies that are licensed in Indiana. The board may establish the requirements and guidelines for the pilot program.

(c) Before June 30, 2007, the Indiana board of pharmacy established by IC 25-26-13-3 shall conduct a study of the electronic pedigree pilot program. The study must include consultation with manufacturers, distributors, and pharmacies that participate in the electronic pedigree pilot program. The study may include the consultation with manufacturers, distributors, and pharmacies that do not participate in the electronic pedigree pilot program. Based on the results of the study, the board shall determine a date to implement a mandatory electronic pedigree program. However, the board may not implement a mandatory electronic pedigree program until after the board has completed the study under this

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subsection.

(d) This SECTION expires December 31, 2007."

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 590 as reprinted February 11, 2005.)

BECKER, Chair

Committee Vote: yeas 10, nays 0.

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