

**CONFERENCE COMMITTEE REPORT
DIGEST FOR ESB 590**

Citations Affected: IC 16-18-2; IC 16-28-11-4; IC 16-42; IC 25-26; IC 27-13-38-2; IC 35-48-3-9; IC 35-48-7-5; IC 35-48-7-8.

Synopsis: Electronic prescriptions. Conference committee report for ESB 590. Allows: (1) the electronic transmission of prescriptions and instructions related to the prescriptions; and (2) the transmission of prescriptions for schedule III, IV, and V controlled substances by facsimile. Provides 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 a process for approving electronic data intermediaries. **(This conference committee report removes provisions concerning wholesale drug distribution.)**

Effective: July 1, 2005.

CONFERENCE COMMITTEE REPORT

MADAM PRESIDENT:

Your Conference Committee appointed to confer with a like committee from the House upon Engrossed House Amendments to Engrossed Senate Bill No. 590 respectfully reports that said two committees have conferred and agreed as follows to wit:

that the Senate recede from its dissent from all House amendments and that the Senate now concur in all House amendments to the bill and that the bill be further amended as follows:

- 1 Delete everything after the enacting clause and insert the following:
2 SECTION 1. IC 16-18-2-106.3 IS ADDED TO THE INDIANA
3 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
4 [EFFECTIVE JULY 1, 2005]: **Sec. 106.3. For purposes of IC 16-42-3**
5 **and IC 16-42-22, "electronic signature" means an electronic sound,**
6 **symbol, or process:**
7 (1) attached to or logically associated with an electronically
8 transmitted prescription or order; and
9 (2) executed or adopted by a person;
10 with the intent to sign the electronically transmitted prescription
11 or order.
12 SECTION 2. IC 16-18-2-106.4 IS ADDED TO THE INDIANA
13 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
14 [EFFECTIVE JULY 1, 2005]: **Sec. 106.4. For purposes of**
15 **IC 16-42-3, IC 16-42-19, and IC 16-42-22, "electronically**
16 **transmitted" or "electronic transmission" means the transmission**
17 **of a prescription in electronic form. The term does not include**
18 **transmission of a prescription by facsimile.**
19 SECTION 3. IC 16-28-11-4 IS AMENDED TO READ AS
20 FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4. A health facility that**
21 **possesses unused medication that meets the requirements of**
22 ~~IC 25-26-13-25(i)(1)~~ **IC 25-26-13-25(j)(1)** through

- 1 ~~IC 25-26-13-25(i)(6)~~: **IC 25-26-13-25(j)(6)**:
 2 (1) shall return medication that belonged to a Medicaid recipient;
 3 and
 4 (2) may return other unused medication;
 5 to the pharmacy that dispensed the medication.
 6 SECTION 4. IC 16-42-3-6 IS AMENDED TO READ AS
 7 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 6. (a) This section
 8 applies to a drug intended for use by humans that:
 9 (1) is a habit forming drug to which section 4(4) of this chapter
 10 applies;
 11 (2) because of:
 12 (A) the drug's toxicity or other potential for harmful effect;
 13 (B) the method of the drug's use; or
 14 (C) the collateral measures necessary to the drug's use;
 15 is not safe for use except under the supervision of a practitioner
 16 licensed by law to administer the drug; or
 17 (3) is limited by an approved application under Section 505 of the
 18 Federal Act or section 7 or 8 of this chapter to use under the
 19 professional supervision of a practitioner licensed by law to
 20 administer the drug.
 21 (b) A drug described in subsection (a) may be dispensed only:
 22 (1) upon a written **or an electronically transmitted** prescription
 23 of a practitioner licensed by law to administer the drug;
 24 (2) upon an oral prescription of the practitioner that is reduced
 25 promptly to writing and filed by the ~~pharmacist~~; **pharmacist or**
 26 **pharmacist intern (as defined in IC 25-26-13-2)**; or
 27 (3) by refilling a ~~written or oral~~ prescription if the refilling is
 28 authorized by the prescriber either in the original prescription, **by**
 29 **an electronically transmitted order that is recorded in an**
 30 **electronic format**, or by oral order that is reduced promptly to
 31 writing **or is entered into an electronic format** and filed by the
 32 pharmacist **or pharmacist intern (as defined in IC 25-26-13-2)**.
 33 (c) If a prescription for a drug described in subsection (a) does not
 34 indicate how many times the prescription may be refilled, if any, the
 35 prescription may not be refilled unless the pharmacist is subsequently
 36 authorized to do so by the practitioner.
 37 (d) The act of dispensing a drug contrary to subsection (a), (b), or (c)
 38 is considered to be an act that results in a drug being misbranded while
 39 held for sale.
 40 (e) A drug dispensed by filling or refilling a ~~written or oral~~
 41 prescription of a practitioner licensed by law to administer the drug is
 42 exempt from the requirements of section 4(2), 4(3), 4(4), 4(5), 4(6),
 43 4(7), 4(8), and 4(9) of this chapter if the drug bears a label containing
 44 the following:
 45 (1) The name and address of the dispenser.
 46 (2) The serial number and date of the prescription or of the
 47 prescription's filling.
 48 (3) The name of the drug's prescriber and, if stated in the
 49 prescription, the name of the patient.
 50 (4) The directions for use and cautionary statements, if any,
 51 contained in the prescription.

1 This exemption does not apply to any drugs dispensed in the course of
2 the conduct of a business of dispensing drugs pursuant to diagnosis by
3 mail or to a drug dispensed in violation of subsection (a), (b), (c), or (d).

4 (f) The state department may adopt rules to remove drugs subject to
5 section 4(4) of this chapter, section 7 of this chapter, or section 8 of this
6 chapter from the requirements of subsections (a) through (d) when the
7 requirements are not necessary for the protection of public health.
8 Drugs removed from the prescription requirements of the Federal Act
9 by regulations issued under the Federal Act may also, by rules adopted
10 by the state department, be removed from the requirement of
11 subsections (a) through (d).

12 (g) A drug that is subject to subsections (a) through (d) is considered
13 to be misbranded if at any time before dispensing the drug's label fails
14 to bear the statement "Caution: Federal Law Prohibits Dispensing
15 Without Prescription" or "Caution: State Law Prohibits Dispensing
16 Without Prescription". A drug to which subsections (a) through (d) ~~does~~
17 **do** not apply is considered to be misbranded if, at any time before
18 dispensing, the drug's label bears the caution statement described in this
19 subsection.

20 (h) This section does not relieve a person from a requirement
21 prescribed by or under authority of law with respect to drugs included
22 within the classifications of narcotic drugs or marijuana as defined in
23 the applicable federal and state laws relating to narcotic drugs and
24 marijuana.

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

28 SECTION 5. IC 16-42-3-9 IS AMENDED TO READ AS
29 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 9. (a) Sections 7 and
30 8 of this chapter do not apply to the following:

31 (1) To a drug dispensed on a written **or an electronically**
32 **transmitted** prescription signed by **or with an electronic**
33 **signature** of a physician, dentist, or veterinarian (except a drug
34 dispensed in the course of the conduct of a business of dispensing
35 drugs pursuant to diagnosis by mail) if the physician, dentist, or
36 veterinarian is licensed by law to administer the drug, and the drug
37 bears a label containing the name and place of business of the
38 dispenser, the serial number and date of the prescription, and the
39 name of the physician, dentist, or veterinarian.

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

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

48 (4) To any drug that is licensed under the Public Health Service
49 Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et
50 seq.) or under the Animal Virus-Serum Toxin Act of March 4,
51 1913 (13 Stat. 832; 21 U.S.C. 151 et seq.).

- 1 (5) To a drug subject to section 4(10) of this chapter.
- 2 (b) Rules exempting drugs intended for investigational use under
3 subsection (a)(2) may, within the discretion of the state department
4 among other conditions relating to the protection of the public health,
5 provide for conditioning the exemption upon the following:
- 6 (1) The submission to the state department, before any clinical
7 testing of a new drug is undertaken, of reports by the manufacturer
8 or the sponsor of the investigation of the drug or preclinical tests,
9 including tests on animals, of the drug adequate to justify the
10 proposed clinical testing.
- 11 (2) The manufacturer or the sponsor of the investigation of a new
12 drug proposed to be distributed to investigators for clinical testing
13 obtaining a signed agreement from each of the investigators that
14 patients to whom the drug is administered will be under the
15 manufacturer's or sponsor's personal supervision or under the
16 supervision of investigators responsible to the manufacturer or
17 sponsor and that the manufacturer or sponsor will not supply the
18 drug to any other investigator or to clinics for administration to
19 human beings.
- 20 (3) The establishment and maintenance of the records and the
21 making of the reports to the state department by the manufacturer
22 or the sponsor of the investigation of the drug of data (including
23 analytical reports by investigators) obtained as the result of the
24 investigational use of the drug that the state department finds will
25 enable the state department to evaluate the safety and effectiveness
26 of the drug if an application is filed under section 8 of this chapter.
- 27 (c) Rules exempting drugs intended for investigational use under
28 subsection (a)(2) must provide that the exemption is conditioned upon
29 the manufacturer or the sponsor of the investigation requiring that
30 experts using the drugs for investigational purposes certify to the
31 manufacturer or sponsor that the experts will inform any human beings
32 to whom the drugs or any controls used in connection with the drugs
33 are being administered that the drugs are being used for investigational
34 purposes and will obtain the consent of the human beings or their
35 representatives, except where they consider it not feasible or, in their
36 professional judgment, contrary to the best interests of the human
37 beings.
- 38 (d) This section does not require a clinical investigator to submit
39 directly to the state department reports on the investigational use of
40 drugs. The regulations adopted under Section 505(i) of the Federal Act
41 are the rules in Indiana. The state may adopt rules, whether or not in
42 accordance with regulations promulgated under the Federal Act.
- 43 SECTION 6. IC 16-42-19-7 IS AMENDED TO READ AS
44 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 7. As used in this
45 chapter, "prescription" means:
- 46 (1) a written order to or for an ultimate user for a drug or device
47 containing the name and address of the patient, the name and
48 strength or size of the drug or device, the amount to be dispensed,
49 adequate directions for the proper use of the drug or device by the
50 patient, and the name of the practitioner, issued and signed by a
51 practitioner; or

1 (2) an order transmitted by other means of communication from a
2 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 format.**

9 SECTION 7. IC 16-42-19-12 IS AMENDED TO READ AS
10 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 12. Except as
11 authorized under ~~IC 25-26-13-25(c);~~ **IC 25-26-13-25(d)**, a person may
12 not refill a prescription or drug order for a legend drug except in the
13 manner designated on the prescription or drug order or by the
14 authorization of the practitioner.

15 SECTION 8. IC 16-42-22-3 IS AMENDED TO READ AS
16 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 3. As used in this
17 chapter, "customer" means the individual for whom a prescription is
18 written **or electronically transmitted** or the individual's representative.

19 SECTION 9. IC 16-42-22-6 IS AMENDED TO READ AS
20 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 6. **(a)** Each written
21 prescription issued by a practitioner must have two (2) signature lines
22 printed at the bottom of the prescription form, one (1) of which must be
23 signed by the practitioner for the prescription to be valid. Under the
24 blank line on the left side of the form must be printed the words
25 "Dispense as written.". Under the blank line on the right side of the
26 form must be printed the words "May substitute.".

27 **(b) Each electronically transmitted prescription issued by a**
28 **practitioner must:**

29 **(1) have an electronic signature; and**

30 **(2) include the electronically transmitted instructions**
31 **"Dispense as written." or "May substitute.".**

32 SECTION 10. IC 16-42-22-8 IS AMENDED TO READ AS
33 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 8. (a) For substitution
34 to occur for a prescription other than a prescription filled under the
35 Medicaid program (42 U.S.C. 1396 et seq.), the children's health
36 insurance program established under IC 12-17.6-2, or the Medicare
37 program (42 U.S.C. 1395 et seq.):

38 (1) the practitioner must:

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

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

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

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

46 SECTION 11. IC 16-42-22-9 IS AMENDED TO READ AS
47 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 9. If the practitioner
48 communicates instructions to the pharmacist orally **or electronically**,
49 the pharmacist shall:

50 **(1) indicate the instructions in the pharmacist's own handwriting on**
51 **the written copy of the prescription order; or**

1 **(2) record the electronically transmitted instructions in an**
 2 **electronic format.**

3 SECTION 12. IC 16-42-22-10 IS AMENDED TO READ AS
 4 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 10. (a) If a prescription
 5 is filled under the Medicaid program (42 U.S.C. 1396 et seq.), the
 6 children's health insurance program established under IC 12-17.6-2, or
 7 the Medicare program (42 U.S.C. 1395 et seq.), the pharmacist shall
 8 substitute a generically equivalent drug product and inform the
 9 customer of the substitution if the substitution would result in a lower
 10 price unless:

11 (1) the words "Brand Medically Necessary" are:
 12 (A) written in the practitioner's own writing on the form; or
 13 (B) **electronically transmitted with an electronically**
 14 **transmitted prescription; or**
 15 (2) the practitioner has indicated that the pharmacist may not
 16 substitute a generically equivalent drug product by:
 17 (A) orally stating that a substitution is not permitted; or
 18 (B) **for an electronically transmitted prescription, indicating**
 19 **with the electronic prescription that a substitution is not**
 20 **permitted.**

21 (b) If a practitioner orally states that a generically equivalent drug
 22 product may not be substituted, the practitioner must subsequently
 23 forward to the pharmacist a written **or electronically transmitted**
 24 prescription with the "Brand Medically Necessary" instruction
 25 appropriately indicated in the physician's own handwriting.

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

28 SECTION 13. IC 16-42-22-12 IS AMENDED TO READ AS
 29 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 12. The pharmacist
 30 shall record on the prescription **in writing or in an electronic format**
 31 **for an electronically transmitted prescription** the name of the
 32 manufacturer or distributor, or both, of the actual drug product
 33 dispensed under this chapter.

34 SECTION 14. IC 25-26-13-2 IS AMENDED TO READ AS
 35 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 2. As used in this
 36 chapter:

37 "Board" means the Indiana board of pharmacy.

38 "Controlled drugs" are those drugs on schedules I through V of the
 39 Federal Controlled Substances Act or on schedules I through V of
 40 IC 35-48-2.

41 "Counseling" means effective communication between a pharmacist
 42 and a patient concerning the contents, drug to drug interactions, route,
 43 dosage, form, directions for use, precautions, and effective use of a
 44 drug or device to improve the therapeutic outcome of the patient
 45 through the effective use of the drug or device.

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

49 "Drug" means:

50 (1) articles or substances recognized in the official United States
 51 Pharmacopoeia, official National Formulary, official Homeopathic

- 1 Pharmacopoeia of the United States, or any supplement to any of
2 them;
- 3 (2) articles or substances intended for use in the diagnosis, cure,
4 mitigation, treatment, or prevention of disease in man or animals;
- 5 (3) articles other than food intended to affect the structure or any
6 function of the body of man or animals; or
- 7 (4) articles intended for use as a component of any article specified
8 in subdivisions (1) through (3) and devices.
- 9 "Drug order" means a written order in a hospital or other health care
10 institution for an ultimate user for any drug or device, issued and signed
11 by a practitioner, or an order transmitted by other means of
12 communication from a practitioner, which is immediately reduced to
13 writing by the pharmacist, registered nurse, or other licensed health care
14 practitioner authorized by the hospital or institution. The order shall
15 contain the name and bed number of the patient; the name and strength
16 or size of the drug or device; unless specified by individual institution
17 policy or guideline, the amount to be dispensed either in quantity or
18 days; adequate directions for the proper use of the drug or device when
19 it is administered to the patient; and the name of the prescriber.
- 20 "Drug regimen review" means the retrospective, concurrent, and
21 prospective review by a pharmacist of a patient's drug related history
22 that includes the following areas:
- 23 (1) Evaluation of prescriptions or drug orders and patient records
24 for drug allergies, rational therapy contradictions, appropriate dose
25 and route of administration, appropriate directions for use, or
26 duplicative therapies.
- 27 (2) Evaluation of prescriptions or drug orders and patient records
28 for drug-drug, drug-food, drug-disease, and drug-clinical laboratory
29 interactions.
- 30 (3) Evaluation of prescriptions or drug orders and patient records
31 for adverse drug reactions.
- 32 (4) Evaluation of prescriptions or drug orders and patient records
33 for proper utilization and optimal therapeutic outcomes.
- 34 "Drug utilization review" means a program designed to measure and
35 assess on a retrospective and prospective basis the proper use of drugs.
- 36 "Device" means an instrument, apparatus, implement, machine,
37 contrivance, implant, in vitro reagent, or other similar or related article
38 including any component part or accessory, which is:
- 39 (1) recognized in the official United States Pharmacopoeia, official
40 National Formulary, or any supplement to them;
- 41 (2) intended for use in the diagnosis of disease or other conditions
42 or the cure, mitigation, treatment, or prevention of disease in man
43 or other animals; or
- 44 (3) intended to affect the structure or any function of the body of
45 man or other animals and which does not achieve any of its
46 principal intended purposes through chemical action within or on
47 the body of man or other animals and which is not dependent upon
48 being metabolized for the achievement of any of its principal
49 intended purposes.
- 50 **"Electronic data intermediary" means an entity that provides the**
51 **infrastructure that connects a computer system or another**

1 **electronic device used by a prescribing practitioner with a**
2 **computer system or another electronic device used by a pharmacy**
3 **to facilitate the secure transmission of:**

- 4 (1) **an electronic prescription order;**
- 5 (2) **a refill authorization request;**
- 6 (3) **a communication; and**
- 7 (4) **other patient care information;**

8 **between a practitioner and a pharmacy.**

9 **"Electronic signature" means an electronic sound, symbol, or**
10 **process:**

- 11 (1) **attached to or logically associated with a record; and**
- 12 (2) **executed or adopted by a person;**

13 **with the intent to sign the record.**

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

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

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

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

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

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

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

32 "Pharmacist" means a person licensed under this chapter.

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

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

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

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

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 order
9 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, sale,
13 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 of
20 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;

43 (6) the name of the practitioner; and

44 (7) ~~the signature of the practitioner~~ if the prescription:

45 (A) is in written form, **the signature of the practitioner; or**

46 (B) **is in electronic form, the electronic signature of the**
47 **practitioner.**

48 "Qualifying pharmacist" means the pharmacist who will qualify the
49 pharmacy by being responsible to the board for the legal operations of
50 the pharmacy under the permit.

51 "Record" means all papers, letters, memoranda, notes, prescriptions,

1 drug orders, invoices, statements, patient medication charts or files,
 2 computerized records, or other written indicia, documents, or objects
 3 which are used in any way in connection with the purchase, sale, or
 4 handling of any drug or device.

5 "Sale" means every sale and includes:

- 6 (1) manufacturing, processing, transporting, handling, packaging,
 7 or any other production, preparation, or repackaging;
- 8 (2) exposure, offer, or any other proffer;
- 9 (3) holding, storing, or any other possession;
- 10 (4) dispensing, giving, delivering, or any other supplying; and
- 11 (5) applying, administering, or any other using.

12 SECTION 15. IC 25-26-13-4 IS AMENDED TO READ AS
 13 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 4. (a) The board may:

- 14 (1) promulgate rules and regulations under IC 4-22-2 for
 15 implementing and enforcing this chapter;
- 16 (2) establish requirements and tests to determine the moral,
 17 physical, intellectual, educational, scientific, technical, and
 18 professional qualifications for applicants for pharmacists' licenses;
- 19 (3) refuse to issue, deny, suspend, or revoke a license or permit or
 20 place on probation or fine any licensee or permittee under this
 21 chapter;
- 22 (4) regulate the sale of drugs and devices in the state of Indiana;
- 23 (5) impound, embargo, confiscate, or otherwise prevent from
 24 disposition any drugs, medicines, chemicals, poisons, or devices
 25 which by inspection are deemed unfit for use or would be
 26 dangerous to the health and welfare of the citizens of the state of
 27 Indiana; the board shall follow those embargo procedures found in
 28 IC 16-42-1-18 through IC 16-42-1-31, and persons may not refuse
 29 to permit or otherwise prevent members of the board or their
 30 representatives from entering such places and making such
 31 inspections;
- 32 (6) prescribe minimum standards with respect to physical
 33 characteristics of pharmacies, as may be necessary to the
 34 maintenance of professional surroundings and to the protection of
 35 the safety and welfare of the public;
- 36 (7) subject to IC 25-1-7, investigate complaints, subpoena
 37 witnesses, schedule and conduct hearings on behalf of the public
 38 interest on any matter under the jurisdiction of the board;
- 39 (8) prescribe the time, place, method, manner, scope, and subjects
 40 of licensing examinations which shall be given at least twice
 41 annually; and
- 42 (9) perform such other duties and functions and exercise such other
 43 powers as may be necessary to implement and enforce this chapter.

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

- 45 (1) Establishing standards for the competent practice of pharmacy.
- 46 (2) Establishing the standards for a pharmacist to counsel
 47 individuals regarding the proper use of drugs.

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

- 50 (1) the board has adopted rules which set forth the procedures and
 51 standards governing the grant or denial of a temporary variance;

1 and
 2 (2) the board sets forth in writing the reasons for a grant or denial
 3 of a temporary variance.

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

8 **(1) Privacy protection for the practitioner and the**
 9 **practitioner's patient.**

10 **(2) Security of the electronic transmission.**

11 **(3) A process for approving electronic data intermediaries for**
 12 **the electronic transmission of prescriptions.**

13 **(4) Use of a practitioner's United States Drug Enforcement**
 14 **Agency registration number.**

15 **(5) Protection of the practitioner from identity theft or**
 16 **fraudulent use of the practitioner's prescribing authority.**

17 SECTION 16. IC 25-26-13-25 IS AMENDED TO READ AS
 18 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 25. (a) All original
 19 prescriptions, whether in written or electronic format, shall be
 20 numbered and maintained in numerical and chronological order, or in
 21 a manner approved by the board and accessible for at least two (2)
 22 years in the pharmacy. A prescription transmitted from a practitioner by
 23 means of communication other than writing must immediately be
 24 reduced to writing or recorded in an electronic format by the
 25 pharmacist. The files shall be open for inspection to any member of the
 26 board or its duly authorized agent or representative.

27 **(b) A prescription may be electronically transmitted from the**
 28 **practitioner by computer or another electronic device to a**
 29 **pharmacy that is licensed under this article or any other state or**
 30 **territory. An electronic data intermediary that is approved by the**
 31 **board:**

32 **(1) may transmit the prescription information between the**
 33 **prescribing practitioner and the pharmacy;**

34 **(2) may archive copies of the electronic information related to**
 35 **the transmissions as necessary for auditing and security**
 36 **purposes; and**

37 **(3) must maintain patient privacy and confidentiality of all**
 38 **archived information as required by applicable state and**
 39 **federal laws.**

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

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

51 **(1) The pharmacist has made every reasonable effort to contact the**

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

- 1 (10) The drug prescribed is not a controlled substance.
 2 A pharmacist may not refill a prescription under this subsection if the
 3 practitioner has designated on the prescription form the words "No
 4 Emergency Refill".
- 5 ~~(d)~~ (e) When refilling a prescription, the refill record shall include:
 6 (1) the date of the refill;
 7 (2) the quantity dispensed if other than the original quantity; and
 8 (3) the dispenser's identity on:
 9 (A) the original prescription form; or
 10 (B) another board approved, uniformly maintained, readily
 11 retrievable record.
- 12 ~~(e)~~ (f) The original prescription form or the other board approved
 13 record described in subsection ~~(d)~~ (e) must indicate by the number of
 14 the original prescription the following information:
 15 (1) The name and dosage form of the drug.
 16 (2) The date of each refill.
 17 (3) The quantity dispensed.
 18 (4) The identity of the pharmacist who dispensed the refill.
 19 (5) The total number of refills for that prescription.
- 20 ~~(f)~~ (g) A prescription is valid for not more than one (1) year after the
 21 original date of issue.
- 22 ~~(g)~~ (h) A pharmacist may not knowingly dispense a prescription after
 23 the demise of the practitioner, unless in the pharmacist's professional
 24 judgment it is in the best interest of the patient's health.
- 25 ~~(h)~~ (i) A pharmacist may not knowingly dispense a prescription after
 26 the demise of the patient.
- 27 ~~(i)~~ (j) A pharmacist or a pharmacy shall not resell, reuse, or
 28 redistribute a medication that is returned to the pharmacy after being
 29 dispensed unless the medication:
 30 (1) was dispensed to a patient:
 31 (A) residing in an institutional facility (as defined in 856
 32 IAC 1-28.1-1(6)); or
 33 (B) in a hospice program under IC 16-25;
 34 (2) was properly stored and securely maintained according to
 35 sound pharmacy practices;
 36 (3) is returned unopened and:
 37 (A) was dispensed in the manufacturer's original:
 38 (i) bulk, multiple dose container with an unbroken tamper
 39 resistant seal; or
 40 (ii) unit dose package; or
 41 (B) was packaged by the dispensing pharmacy in a:
 42 (i) multiple dose blister container; or
 43 (ii) unit dose package;
 44 (4) was dispensed by the same pharmacy as the pharmacy
 45 accepting the return;
 46 (5) is not expired; and
 47 (6) is not a controlled substance (as defined in IC 35-48-1-9),
 48 unless the pharmacy holds a Type II permit (as described in section
 49 17 of this chapter).
- 50 ~~(j)~~ (k) A pharmacist may use the pharmacist's professional judgment
 51 as to whether to accept medication for return under this section.

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

3 SECTION 17. IC 25-26-13-25.5 IS ADDED TO THE INDIANA
4 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
5 [EFFECTIVE JULY 1, 2005]: **Sec. 25.5. A prescription may be**
6 **transmitted electronically from a practitioner to a pharmacy only**
7 **through the use of an electronic data intermediary approved by the**
8 **board.**

9 SECTION 18. IC 25-26-15-10 IS AMENDED TO READ AS
10 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 10. As used in this
11 chapter, "prescription" means a written order or an order transmitted by
12 other means of communication that is immediately reduced to writing
13 by the pharmacist **or, for electronically transmitted orders, recorded**
14 **in an electronic format** from an optometrist to or for an ultimate user
15 for a drug or device, containing:

- 16 (1) the name and address of the patient;
- 17 (2) the date of issue;
- 18 (3) the name and strength or size (if applicable) of the drug or
19 device;
- 20 (4) the amount to be dispensed (unless indicated by directions and
21 duration of therapy);
- 22 (5) adequate directions for the proper use of the drug or device by
23 the patient;
- 24 (6) the name and certification number of the prescribing
25 optometrist; and
- 26 (7) ~~the signature of the optometrist~~ if the prescription:
27 **(A) is in written form, the signature of the optometrist; or**
28 **(B) is in electronic form, the electronic signature of the**
29 **optometrist.**

30 SECTION 19. IC 25-26-20-4 IS AMENDED TO READ AS
31 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 4. (a) Except as
32 provided in subsections (b) and (c), unadulterated drugs that meet the
33 requirements set forth in ~~IC 25-26-13-25(i)~~ **IC 25-26-13-25(j)** may be
34 donated without a prescription or drug order to the regional drug
35 repository program by the following:

- 36 (1) A pharmacist or pharmacy.
- 37 (2) A wholesale drug distributor.
- 38 (3) A hospital licensed under IC 16-21.
- 39 (4) A health care facility (as defined in IC 16-18-2-161).
- 40 (5) A hospice.
- 41 (6) A practitioner.
- 42 (b) An unadulterated drug that:
43 (1) was returned under IC 25-26-13-25; and
44 (2) was prescribed for a Medicaid recipient;
45 may not be donated under this section unless the Medicaid program has
46 been credited for the product cost of the drug as provided in policies
47 under the Medicaid program.

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

49 SECTION 20. IC 27-13-38-2 IS AMENDED TO READ AS
50 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 2. Subject to
51 IC 16-42-22:

- 1 (1) a pharmacist shall not substitute; and
 2 (2) a health maintenance organization shall not require the
 3 substitution of;
 4 a different single source brand name drug for a single source brand
 5 name drug written on a prescription form **or electronically transmitted**
 6 **to a pharmacy** unless the substitution is approved by the prescribing
 7 provider.

8 SECTION 21. IC 35-48-3-9 IS AMENDED TO READ AS
 9 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 9. (a) Except for
 10 dosages medically required for a period of not more than forty-eight
 11 (48) hours that are dispensed by or on the direction of a practitioner or
 12 medication dispensed directly by a practitioner, other than a pharmacy,
 13 to an ultimate user, no controlled substance in schedule II may be
 14 dispensed without the written prescription of a practitioner.

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

20 (c) Except for dosages medically required for a period of not more
 21 than forty-eight (48) hours that are dispensed by or on the direction of
 22 a practitioner, or medication dispensed directly by a practitioner, other
 23 than a pharmacy, to an ultimate user, a controlled substance included
 24 in schedule III or IV, which is a prescription drug as determined under
 25 IC 16-42-19, shall not be dispensed without a written or oral
 26 prescription of a practitioner. The prescription shall not be filled or
 27 refilled more than six (6) months after the date thereof or be refilled
 28 more than five (5) times, unless renewed by the practitioner.
 29 **Prescriptions for schedule III, IV, and V controlled substances may**
 30 **be transmitted by facsimile from the practitioner or the agent of**
 31 **the practitioner to a pharmacy. The facsimile prescription is**
 32 **equivalent to an original prescription to the extent permitted under**
 33 **federal law.**

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

36 SECTION 22. IC 35-48-7-5 IS AMENDED TO READ AS
 37 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 5. As used in this
 38 chapter, "identification number" refers to **the following**:

- 39 (1) The unique number contained on any of the following:
 40 ~~(1)~~ (A) A valid driver's license of a recipient or a recipient's
 41 representative issued under Indiana law or the law of any other
 42 state.
 43 ~~(2)~~ (B) A recipient's or a recipient representative's valid military
 44 identification card.
 45 ~~(3)~~ (C) A valid identification card of a recipient or a recipient's
 46 representative issued by:
 47 ~~(A)~~ (i) the bureau of motor vehicles ~~and~~ as described in
 48 IC 9-24-16-3; or
 49 ~~(B)~~ (ii) any other state and that is similar to the identification
 50 card issued by the bureau of motor vehicles.
 51 ~~(4)~~ (D) If the recipient is an animal:

- 1 ~~(A)~~ **(i)** the valid driver's license issued under Indiana law or the
 2 law of any other state;
 3 ~~(B)~~ **(ii)** the valid military identification card; or
 4 ~~(C)~~ **(iii)** the valid identification card issued by the bureau of
 5 motor vehicles and described in IC 9-24-16-3 or a valid
 6 identification card of similar description that is issued by any
 7 other state;
 8 of the animal's owner.
- 9 **(2) The identification number or phrase designated by the**
 10 **central repository.**
- 11 SECTION 23. IC 35-48-7-8 IS AMENDED TO READ AS
 12 FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 8. The advisory
 13 committee shall provide for a controlled substance prescription
 14 monitoring program that includes the following components:
- 15 (1) Each time a controlled substance designated by the advisory
 16 committee under IC 35-48-2-5 through IC 35-48-2-10 is dispensed,
 17 the dispenser shall transmit to the central repository the following
 18 information:
- 19 (A) The recipient's name.
 20 (B) The recipient's or the recipient representative's identification
 21 number **or the identification number or phrase designated by**
 22 **the central repository.**
 23 (C) The recipient's date of birth.
 24 (D) The national drug code number of the controlled substance
 25 dispensed.
 26 (E) The date the controlled substance is dispensed.
 27 (F) The quantity of the controlled substance dispensed.
 28 (G) The number of days of supply dispensed.
 29 (H) The dispenser's United States Drug Enforcement Agency
 30 registration number.
 31 (I) The prescriber's United States Drug Enforcement Agency
 32 registration number.
 33 (J) An indication as to whether the prescription was transmitted
 34 to the pharmacist orally or in writing.
- 35 (2) The information required to be transmitted under this section
 36 must be transmitted not more than fifteen (15) days after the date
 37 on which a controlled substance is dispensed.
- 38 (3) A dispenser shall transmit the information required under this
 39 section by:
- 40 (A) an electronic device compatible with the receiving device of
 41 the central repository;
 42 (B) a computer diskette;
 43 (C) a magnetic tape; or
 44 (D) a pharmacy universal claim form;
 45 that meets specifications prescribed by the advisory committee.
- 46 (4) The advisory committee may require that prescriptions for
 47 controlled substances be written on a one (1) part form that cannot
 48 be duplicated. However, the advisory committee may not apply
 49 such a requirement to prescriptions filled at a pharmacy with a
 50 Type II permit (as described in IC 25-26-13-17) and operated by a
 51 hospital licensed under IC 16-21, or prescriptions ordered for and

1 dispensed to bona fide enrolled patients in facilities licensed under
2 IC 16-28. The committee may not require multiple copy
3 prescription forms and serially numbered prescription forms for
4 any prescriptions written. The committee may not require different
5 prescription forms for any individual drug or group of drugs.
6 Prescription forms required under this subdivision must be jointly
7 approved by the committee and by the Indiana board of pharmacy
8 established by IC 25-26-13-3.
9 (5) The costs of the program.
(Reference is to ESB 590 as printed March 18, 2005.)

Conference Committee Report
on
Engrossed Senate Bill 590

Signed by:

Senator Riegsecker
Chairperson

Representative Budak

Senator Simpson

Representative Brown C

Senate Conferees

House Conferees