Reprinted
February 11, 2005

SENATE BILL No. 590

DIGEST OF SB 590 (Updated February 10, 2005 2:44 pm - DI 110)

Citations Affected: IC 16-18; IC 16-28; IC 16-42; IC 25-26; IC 27-13; IC 35-48.

Synopsis: Electronic drug prescriptions. 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.

Effective: July 1, 2005.

Riegsecker, Simpson

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.

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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.

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:

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

(1) attached to or logically associated with an electronically transmitted prescription or order; and

(2) executed or adopted by a person;

with the intent to sign the electronically transmitted prescription or order.

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.**

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

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

(2) may return other unused medication;

to the pharmacy that dispensed the medication.

SECTION 4. IC 16-42-3-6 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 6. (a) This section applies to a drug intended for use by humans that:

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

(2) because of:

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

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

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

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

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

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

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

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

(3) by refilling a ~~written or oral~~ prescription if the refilling is authorized by the prescriber either in the original prescription, **by an electronically transmitted order that is recorded in an electronic format,** or by oral order that is reduced promptly to writing and filed by the pharmacist.

(c) If a prescription for a drug described in subsection (a) does not indicate how many times the prescription may be refilled, if any, the prescription may not be refilled unless the pharmacist is subsequently authorized to do so by the practitioner.

(d) The act of dispensing a drug contrary to subsection (a), (b), or (c) is considered to be an act that results in a drug being misbranded while held for sale.

(e) A drug dispensed by filling or refilling a ~~written or oral~~ prescription of a practitioner licensed by law to administer the drug is exempt from the requirements of section 4(2), 4(3), 4(4), 4(5), 4(6), 4(7), 4(8), and 4(9) of this chapter if the drug bears a label containing the following:

(1) The name and address of the dispenser.

(2) The serial number and date of the prescription or of the prescription's filling.

(3) The name of the drug's prescriber and, if stated in the prescription, the name of the patient.

(4) The directions for use and cautionary statements, if any, contained in the prescription.

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

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

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

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

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

SECTION 5. IC 16-42-3-9 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 9. (a) Sections 7 and 8

of this chapter do not apply to the following:

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

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

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

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

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

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

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

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

(3) The establishment and maintenance of the records and the

making of the reports to the state department by the manufacturer or the sponsor of the investigation of the drug of data (including analytical reports by investigators) obtained as the result of the investigational use of the drug that the state department finds will enable the state department to evaluate the safety and effectiveness of the drug if an application is filed under section 8 of this chapter.

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

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

SECTION 6. IC 16-42-19-7 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 7. As used in this chapter, "prescription" means:

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

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

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

(B) for an electronically transmitted prescription:

(i) has the electronic signature of the practitioner; and

(ii) is recorded by the pharmacist in an electronic format.

SECTION 7. IC 16-42-19-12 IS AMENDED TO READ AS

FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 12. Except as authorized under ~~IC 25-26-13-25(c),~~ **IC 25-26-13-25(d),** a person may not refill a prescription or drug order for a legend drug except in the manner designated on the prescription or drug order or by the authorization of the practitioner.

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

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

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

(1) have an electronic signature; and

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

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

(1) the practitioner must:

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

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

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

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

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

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

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

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

(1) the words "Brand Medically Necessary" are:

(A) written in the practitioner's own writing on the form; or

(B) electronically transmitted with an electronically transmitted prescription; or

(2) the practitioner has indicated that the pharmacist may not substitute a generically equivalent drug product by:

(A) orally stating that a substitution is not permitted; **or**

(B) for an electronically transmitted prescription, indicating with the electronic prescription that a substitution is not permitted.

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

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

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

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

"Board" means the Indiana board of pharmacy.

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

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

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

"Drug" means:

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

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

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

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

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

"Drug regimen review" means the retrospective, concurrent, and prospective review by a pharmacist of a patient's drug related history that includes the following areas:

(1) Evaluation of prescriptions or drug orders and patient records for drug allergies, rational therapy contradictions, appropriate dose and route of administration, appropriate directions for use, or duplicative therapies.

(2) Evaluation of prescriptions or drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions.

(3) Evaluation of prescriptions or drug orders and patient records

for adverse drug reactions.

(4) Evaluation of prescriptions or drug orders and patient records for proper utilization and optimal therapeutic outcomes.

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

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

(1) recognized in the official United States Pharmacopoeia, official National Formulary, or any supplement to them;

(2) intended for use in the diagnosis of disease or other conditions or the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(3) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

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

(1) an electronic prescription order;

(2) a refill authorization request;

(3) a communication; and

(4) other patient care information;

between a practitioner and a pharmacy.

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

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

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

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

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

(3) The proper and safe storage and distribution of drugs and

devices.

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

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

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

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

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

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

(1) the name and address of the patient;

(2) the date of issue;

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

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

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

(6) the name of the practitioner; and

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

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

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

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

"Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication charts or files,

computerized records, or other written indicia, documents, or objects which are used in any way in connection with the purchase, sale, or handling of any drug or device.

"Sale" means every sale and includes:

(1) manufacturing, processing, transporting, handling, packaging, or any other production, preparation, or repackaging;

(2) exposure, offer, or any other proffer;

(3) holding, storing, or any other possession;

(4) dispensing, giving, delivering, or any other supplying; and

(5) applying, administering, or any other using.

SECTION 15. 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:

(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.

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

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

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

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

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

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

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

(1) The pharmacist has made every reasonable effort to contact the original prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(2) The pharmacist believes that, under the circumstances, failure to provide a refill would be seriously detrimental to the patient's health.

(3) The original prescription authorized a refill but a refill would otherwise be invalid for either of the following reasons:

(A) All of the authorized refills have been dispensed.

(B) The prescription has expired under subsection ~~(f).~~ **(g).**

(4) The prescription for which the patient requests the refill was:

(A) originally filled at the pharmacy where the request for a refill is received and the prescription has not been transferred for refills to another pharmacy at any time; or

(B) filled at or transferred to another location of the same pharmacy or its affiliate owned by the same parent corporation if the pharmacy filling the prescription has full access to prescription and patient profile information that is simultaneously and continuously updated on the parent corporation's information system.

(5) The drug is prescribed for continuous and uninterrupted use and the pharmacist determines that the drug is being taken properly in accordance with IC 25-26-16.

(6) The pharmacist shall document the following information regarding the refill:

(A) The information required for any refill dispensed under subsection ~~(d).~~ **(e).**

(B) The dates and times that the pharmacist attempted to contact the prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(C) The fact that the pharmacist dispensed the refill without the authorization of a licensed practitioner.

(7) The pharmacist notifies the original prescribing practitioner of the refill and the reason for the refill by the practitioner's next business day after the refill has been made by the pharmacist.

(8) Any pharmacist initiated refill under this subsection may not be for more than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day. However, a pharmacist may dispense a drug in an amount greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day if:

(A) the drug is packaged in a form that requires the pharmacist to dispense the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day; or

(B) the pharmacist documents in the patient's record the amount of the drug dispensed and a compelling reason for dispensing the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day.

(9) Not more than one (1) pharmacist initiated refill is dispensed under this subsection for a single prescription.

(10) The drug prescribed is not a controlled substance.

A pharmacist may not refill a prescription under this subsection if the practitioner has designated on the prescription form the words "No Emergency Refill".

~~(d)~~ **(e)** When refilling a prescription, the refill record shall include:

(1) the date of the refill;

(2) the quantity dispensed if other than the original quantity; and

(3) the dispenser's identity on:

(A) the original prescription form; or

(B) another board approved, uniformly maintained, readily retrievable record.

~~(c)~~ **(f)** The original prescription form or the other board approved

record described in subsection ~~(d)~~ **(e)** must indicate by the number of the original prescription the following information:

(1) The name and dosage form of the drug.

(2) The date of each refill.

(3) The quantity dispensed.

(4) The identity of the pharmacist who dispensed the refill.

(5) The total number of refills for that prescription.

~~(f)~~ **(g)** A prescription is valid for not more than one (1) year after the original date of issue.

~~(g)~~ **(h)** A pharmacist may not knowingly dispense a prescription after the demise of the practitioner, unless in the pharmacist's professional judgment it is in the best interest of the patient's health.

~~(h)~~ **(i)** A pharmacist may not knowingly dispense a prescription after the demise of the patient.

~~(i)~~ **(j)** A pharmacist or a pharmacy shall not resell, reuse, or redistribute a medication that is returned to the pharmacy after being dispensed unless the medication:

(1) was dispensed to a patient:

(A) residing in an institutional facility (as defined in 856 IAC 1-28.1-1(6)); or

(B) in a hospice program under IC 16-25;

(2) was properly stored and securely maintained according to sound pharmacy practices;

(3) is returned unopened and:

(A) was dispensed in the manufacturer's original:

(i) bulk, multiple dose container with an unbroken tamper resistant seal; or

(ii) unit dose package; or

(B) was packaged by the dispensing pharmacy in a:

(i) multiple dose blister container; or

(ii) unit dose package;

(4) was dispensed by the same pharmacy as the pharmacy accepting the return;

(5) is not expired; and

(6) is not a controlled substance (as defined in IC 35-48-1-9), unless the pharmacy holds a Type II permit (as described in section 17 of this chapter).

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

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

SECTION 17. 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.**

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

(1) the name and address of the patient;

(2) the date of issue;

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

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

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

(6) the name and certification number of the prescribing optometrist; and

(7) ~~the signature of the optometrist~~ if the prescription:

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

(B) is in electronic form, the electronic signature of the optometrist.

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

(1) A pharmacist or pharmacy.

(2) A wholesale drug distributor.

(3) A hospital licensed under IC 16-21.

(4) A health care facility (as defined in IC 16-18-2-161).

(5) A hospice.

(6) A practitioner.

(b) An unadulterated drug that:

(1) was returned under IC 25-26-13-25; and

(2) was prescribed for a Medicaid recipient;

may not be donated under this section unless the Medicaid program has

been credited for the product cost of the drug as provided in policies under the Medicaid program.

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

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

(1) a pharmacist shall not substitute; and

(2) a health maintenance organization shall not require the substitution of;

a different single source brand name drug for a single source brand name drug written on a prescription form **or electronically transmitted to a pharmacy** unless the substitution is approved by the prescribing provider.

SECTION 21. 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. **Prescriptions for schedule III, IV, and V controlled substances may be transmitted by facsimile from the practitioner or the agent of the practitioner to a pharmacy. The facsimile prescription is equivalent to an original prescription to the extent permitted under federal law.**

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

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.

SENATE MOTION

Madam President: I move that Senator Simpson be added 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.

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:

(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.**".

Renumber all SECTIONS consecutively.

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

RIEGSECKER